Understanding Sterilization and Reuse of Medical Devices in Nepal

A thesis submitted in partial fulfilment of the requirements for the Degree of

Doctor of Philosophy in Health Sciences

by

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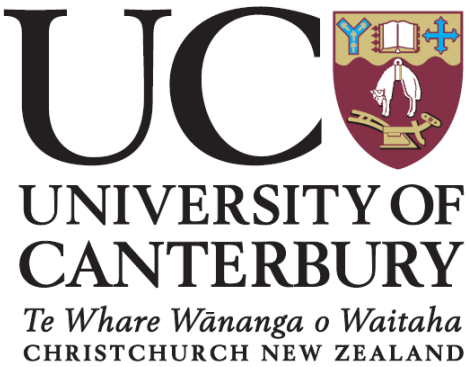

School of Health Sciences

University of Canterbury

2018

Dedicated to the memory of my grandfather

Nanda Lal Panta

(1901 -2000)

Acknowledgements

I am deeply grateful to my supervisors Professor Ann Richardson and Professor Ian Shaw for their guidance and continuous support throughout this journey. Without their guidance, this journey would not have been possible.

Accomplishing this PhD was not just my aspiration; my journey from a rural village in Nepal to the University of Canterbury was also dreamed of by my parents, especially by my father, Mr. Nilmani Panta. I am incredibly thankful to them for their unconditional love and blessings.

I am extremely thankful to my wife, Aparajita, for her incomparable love and support during this journey. She has closely witnessed the ups and downs of this journey and supported me in many ways, though she had to live in Nepal for the most part of this journey. It was not easy for both of us being away from each other for such a long period of time. I deeply appreciate her courage to tackle alone the adverse situation brought by the Nepal Earthquake in April 2015. I am indebted to my father-in-law and mother-in-law for their continued support and blessings during this journey.

Ever since I started my PhD, there was one person in my life who was as excited as I was about every little thing that had to be done. My public health career in Nepal started with his guidance. Mr. Rishi Ram Parajuli helped me to accomplish many crucial activities related to this study, including obtaining a letter of support from the Ministry of Health - Nepal, receiving ethical clearance from the Nepal Health Research Council, conducting field testing of study tools, and carrying out research activities in the field. His untimely demise in August 2017 was one of the most difficult times during this journey, which has left a huge void. He will always be incredibly missed as a wonderful brother, friend and mentor.

I would like to thank Ms Pat Coope for her advice and critical support for all statistical matters, ranging from study design to data analysis. Similarly, I am thankful to Ms Margaret Paterson, Liaison Librarian for Health Sciences, for her support in ensuring the availability of additional books related to this study and in helping with referencing issues. I would also like

to thank Professor Michael Robb for his continued support during this journey as the Head of School, School of Health Sciences, University of Canterbury.

A special thanks goes to Ms Ruth Barratt, Clinical Nurse Specialist Infection Prevention and Control from Christchurch Hospital, for helping me to observe the Theatre Sterile Supply Unit in the hospital and for providing expert advice.

A special gratitude goes out to my wonderful colleagues in the School of Health Sciences, Ms Robyn Johnston, Dr Llyween Couper and Ms Helen Mataiti, for their overwhelming support in these three years and for always encouraging me in many ways to accomplish this work. I am equally grateful to all other colleagues in our post-graduate study room for motivating me continuously. This journey would not have felt the same without all of you.

An important acknowledgement goes to Dr Karna BM Rana for his friendship and all the support he has provided on a day-to-day basis both in and outside the college. I have learnt so much about dedication and perseverance from you.

The presence and support of many other relatives, colleagues and friends in Nepal and New Zealand always remained important to accomplish this very important journey and I am grateful to all of them.

Lastly, I would like to express my gratitude to all the public hospitals and healthcare workers (including support staff) in Nepal who agreed to participate in this study and make this study happen.

Summary

Background: It has been estimated that 7.1% (95% CI 6.5% - 7.8%) and 10.2% (95% CI 9.0% - 13.0%) of hospitalized patients acquire healthcare-associated infections (HAIs) in developed and developing countries respectively. HAIs can cause long-term disability, increase the financial burden for health systems, increase costs for patients and their families, and can also result in deaths. Though scientific estimates of HAIs in Nepal are not available, studies have reported that the proportion of patients developing surgical site infections after undergoing surgery in hospitals in Nepal is high. Reusable medical devices can be a source of such infections, if they are not sterilized adequately. Steam sterilization (autoclaving) is the most commonly used method of sterilizing reusable medical devices in healthcare facilities, including in primary and secondary care hospitals in Nepal. Appropriate strategies and interventions could be developed and implemented for ensuring adequate sterilization of medical devices if the effectiveness of steam sterilization in these hospitals is established, compliance of these hospitals with standard steam sterilization practices is understood, and factors associated with inadequate sterilization of medical devices are known.

Objectives: This study sought to: (i) estimate the effectiveness of steam sterilization practices in primary and secondary care hospitals in Nepal, (ii) understand compliance of these hospitals with standard steam sterilization practices, and (iii) investigate the knowledge and attitudes of healthcare workers towards sterilization and reuse of medical devices.

Methods: A quantitative descriptive cross-sectional study was used for this research. A total of thirteen primary and secondary care public hospitals were selected for this study, using cluster-sample design. Basic information about each of the hospitals was collected using a Hospital Summary Information sheet. Within these hospitals, 189 steam sterilization cycles were evaluated for their effectiveness, using self-contained biological indicators containing 1.3 x 106 spores *Geobacillus stearothermophilus* and class 5 chemical indicators. The same medical device reprocessing cycles were audited using an audit tool for medical device reprocessing with steam sterilization. A knowledge and attitude survey was carried out among healthcare workers, including doctors, nurses, paramedics and autoclave operators; a total of 219 healthcare workers participated in the survey. Descriptive statistical analysis of data was carried out using IBM Statistical Package for the Social Sciences (IBM SPSS statistics 24). The analysis included, but was not limited to, calculation of proportions,

assessing associations between variables, and some regression analyses. Required ethical clearance was obtained from the University of Canterbury Human Ethics Committee and the Nepal Health Research Council to conduct this study.

Results: About 90% of the autoclaves used in primary and secondary care hospitals in Nepal were basic pressure-cooker type autoclaves. The proportion of steam sterilization cycles showing positive results (i.e. ineffective sterilization) with the biological indicators was 71.0% (95% CI 46.8% - 87.2%). Also, a similar proportion (69.8%; 95% CI 44.4% - 87.0%) of steam sterilization cycles showed "reject" results with class 5 chemical indicator. The pressure achieved during the holding period, and the autoclave type, were statistically significantly associated with ineffective steam sterilization. For all primary and secondary care hospitals, the mean percentage compliance with the standard practices for reprocessing of medical devices with steam sterilization was 25.9% (95% CI 21.0% - 30.8%). More than 70% of healthcare workers had appropriate knowledge about key aspects of the sterilization and reuse of medical devices, and overall, the attitudes of healthcare workers towards issues related to sterilization and reuse of medical devices were found to be positive. Compared with nurses, paramedics and office assistants were statistically significantly less likely to have correct knowledge or positive attitudes towards many of the medical device reprocessing issues, adjusted for duration of healthcare work, infection control training, employment status, and practice of autoclave operation.

Conclusion: This study provided an overall picture of steam sterilization and the reuse of medical devices in primary and secondary care public hospitals in Nepal. A high proportion of steam sterilization cycles in these hospitals was ineffective in killing spores of *Geobacillus stearothermophilus*, indicating a possibility of transmission of infectious agents to patients through reusable medical devices. Adequate management and support processes, including appropriate policies, infrastructure, equipment, education, and monitoring are required for ensuring effective sterilization of medical devices in these hospitals.

List of Abbreviations

CDC	Centers for Disease Control and Prevention
CFU	Colony Forming Unit
CI	Confidence Interval
CJD	Creutzfeldt-Jakob Disease
CSSD	Central Sterile Services Department
DDA	Department of Drug Administration
DEFF	Design Effect
FDA	U.S. Food and Drug Administration
HAI	Healthcare Associated Infections
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HLD	High Level Disinfection
ISO	International Organization for Standardization
LMIC	Low and Middle Income Country
LPG	Liquid Petroleum Gas
NHRC	Nepal Health Research Council
NHSS	Nepal Health Sector Strategy
NHTC	National Health Training Center
PPE	Personal Protective Equipment
SAL	Sterility Assurance Level
SSD	Sterile Services Department
SSI	Surgical Site Infection
USAID	United States Agency for International Development
WHO	World Health Organization

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CHAPTER 1. INTRODUCTION

This chapter provides a background to this study. An outline of public healthcare facilities in Nepal is provided and the need for the study is also discussed. The research objectives and research questions are provided, and the organization of the thesis is described at the end of this chapter.

1.1 Healthcare Associated Infections

People go to healthcare facilities to receive appropriate care and treatment for their illness. Sometimes, however, they might also acquire infections known as healthcare-associated infections (HAIs, sometimes also abbreviated as HCAIs) while being treated for their medical conditions. The World Health Organization (WHO) defines HAI as:

> An HAI is an infection that is acquired by a patient during care delivery in a hospital or other health care facility that was not present or incubating on admission. Visitors, family members and health workers can also be affected by HAIs (WHO, 2016c, p. 4).

HAIs are sometimes also known as 'hospital acquired', 'nosocomial' or 'hospital' infections. HAIs are unintended and are considered as an important patient safety issue (Wachter, 2012). It has been estimated that 7.1% (95% CI 6.5% - 7.8%) and 10.2% (95% CI 9.0% - 13.0%) of hospitalized patients acquire HAIs in developed and developing countries respectively (WHO, 2011). Zaidi et al. (2005) documented that the rate of hospital acquired neonatal infections in developing countries is 3-20 times higher than in developed countries.

Sources of HAIs could be patients, healthcare personnel, medical equipment and devices, healthcare environment, or visitors (WHO, 2011). Commonly occurring HAIs are urinary tract infections, surgical site infections (SSIs), skin infections, respiratory infections and bloodstream infections.

SSI is the most frequent type of HAI in developing countries (Allegranzi *et al.*, 2011; WHO, 2011). The cumulative incidence of SSIs in low- and middle-income countries is 1.2 to 23.6

per 100 surgical procedures whereas that for developed countries ranges from 1.2 to 5.2 per 100 surgical procedures (Allegranzi *et al.*, 2011; WHO, 2011). As reported by Allegranzi *et al.* (2011), the pooled cumulative incidence of SSIs in low- and middle-income countries for the period of 1995-2008 was 11.8 (95% CI 8.6 - 16.0) per 100 patients who had undergone surgical procedures. Scientific estimates of HAIs in Nepal are not available. However, a study conducted in a tertiary care hospital in Nepal showed an SSI rate of 7.3 per 100 patients who had undergone general surgical procedures between January 2004 and June 2004 (Giri *et al.*, 2008). Another study conducted in another tertiary care hospital between January 2011 and June 2011 in Nepal showed SSIs in 23.0% of the patients who had undergone open gastrointestinal surgeries (Giri *et al.*, 2013). In addition, Shrestha *et al.* (2016) reported an SSI rate of 2.7 per 100 patients who had undergone elective or emergency surgeries in a university hospital between February 2014 and April 2014. An SSI rate of 11.8 per 100 patients who had undergone head and neck surgeries between April 2013 and April 2015 was reported in another tertiary care hospital in eastern Nepal despite the use of antibiotics before and after surgery (Chapagain *et al.*, 2017). Although it is not clear that the rates reported in the papers from Nepal were calculated in the same way, these findings indicate variations in SSI rates in the hospitals in Nepal. However, the hospitals studied were not randomly selected, so these findings cannot be generalized to all healthcare facilities including primary, secondary and tertiary care private and public healthcare facilities in Nepal.

1.2 Impact of HAIs

HAIs can prolong a patient's stay in the hospital, cause long-term disability, increase the financial burden for health systems, increase costs for patients and their families, and can also result in deaths (WHO, 2011).

Zimlichman *et al.* (2013) estimated that in the US, the total annual costs for five major HAIs (SSIs, ventilator-associated pneumonia, central line-associated bloodstream infections and catheter-associated urinary tract infections) were US$9.8 billion (95% CI $8.3-$11.5 billion), 33.7% of the cost being used for the SSIs. A systematic review conducted by Badia *et al.* (2017) in six European countries found that SSIs were consistently associated with an increase in healthcare costs. Estimates suggest that HAIs may take up as many as 2 million bed-days per annum in Australia (Lee & Bishop, 2013) which illustrates the magnitude of the

economic burden for a country. Another study conducted in Sweden by Rahmqvist *et al.* (2016) found a higher risk of re-admission among patients with HAIs compared with patients with no HAIs i.e. 29.0% vs 16.5%; this study also found that HAIs were associated with increased length of stay and increased healthcare costs; 9.3% of the total bed days and 11.4% of the total costs were attributed to HAIs. Moreover, this study found a 1-year mortality ratio of 1.75 (95% CI 1.45-2.11) for patients with HAIs compared with patients without HAIs. Broex *et al.* (2009) conducted a review and reported that the healthcare cost for a patient with an SSI was approximately double the cost for a patient without an SSI.

Scientific studies assessing financial loss due to HAIs in developing countries are scarce. However, the loss due to HAIs could be proportionately higher in those countries because of the higher rate of HAIs. A study from a South African children's hospital showed annual direct costs of US$ 371,887 related to HAIs which were associated with significant increase in morbidity and mortality of the paediatric patients and two-thirds of paediatric deaths in the hospital (Dramowski, Whitelaw & Cotton, 2016).

1.3 HAIs and Antimicrobial Drug Resistance

A high proportion of microorganisms causing HAIs are resistant to one or more of the antibiotics which are generally prescribed to treat HAIs. Yezli and Li (2012) reported a rapid increase in antimicrobial resistance among bacteria causing HAIs in China with a strong tendency for the development of multidrug resistance. According to Zhang *et al.* (2006), an average increase of 22% in the rate of antimicrobial resistance was reported in China in six years (1994 - 2000) whereas an average increase of 6% was reported in the USA in three years (1999 - 2002). A study reporting data from the National Healthcare Safety Network (NHSN) between 2011 and 2014 at the Centers for Disease Control and Prevention (CDC) found that more than 42 % of *Staphylococcus aureus* isolates associated with SSIs were resistant to selected antimicrobial agents such as oxacillin, methicillin and cefoxitin (Weiner *et al.*, 2016).

Preventing the spread of antimicrobial resistant organisms has become extremely important globally. A Review on Antimicrobial Resistance (2016) estimated that about 10 million deaths per year by 2050 and a cumulative economic loss of 100 trillion USD between 2016

and 2050 would be attributable to antimicrobial resistance if actions are not taken against antimicrobial resistance. The review further estimated that the deaths of about 700,000 people were due to antimicrobial resistance in 2016**.** The problem of antimicrobial resistance has been further exacerbated by the absence of discovery of new classes of antibacterial drugs in the last 30 years (Silver, 2011).

1.4 Reusable Medical Devices and HAIs

1.4.1 Reuse of medical devices in healthcare

Sterile tissues or mucous membranes of the human body come in contact with medical devices or instruments during invasive clinical procedures, such as during surgery. Medical devices are reprocessed before being reused for such procedures to prevent infections associated with medical devices. Reuse of medical devices has contributed to major cost savings across a number of medical disciplines (Kwakye, Pronovost & Makary, 2010). However, reuse of medical devices cannot just be taken as a cost-saving approach to healthcare. In resource-poor settings, it could be the only way of ensuring the availability of medical devices for healthcare services. If medical devices are not reused in those settings, the number of invasive or surgical procedures is likely to decrease (Shuman & Chenoweth, 2012).

Medical devices are reprocessed and reused for most surgical procedures. The volume of surgical procedures is quite large globally. A study estimates that 234·2 (95% CI 187·2 - 281·2) million surgical procedures are carried out globally each year (Weiser *et al.*, 2008). A cluster-based household survey conducted among individuals aged 50 years or above estimated that about 2.1 (95% CI 1.8 - 2.4) million elderly in Nepal have a surgically treatable condition and about 20% of the deaths in the age group were due to conditions potentially treatable by surgical care (Stewart *et al.*, 2015) . Another similar study conducted by Gupta *et al.* (2015) in all age groups reported that 10% (95% CI 8·9% to 11·2%) of respondents had an existing condition requiring surgery and 23% of deaths were caused due to conditions potentially treatable by surgical care. These findings clearly indicate that there is an unmet need for surgical services in Nepal. When surgical services are scaled up to meet the need, usage of medical devices and their reprocessing will also be increased. Surgical

procedures are not limited to higher level healthcare facilities, because minor surgery is now a key component of primary healthcare (Bae, Groen & Kushner, 2011); for example, treatment of open fractures and drainage of abscesses. In addition to minor surgery, medical devices are also used for a wide range of other healthcare activities including diagnosis, prevention, monitoring, treatment or alleviation of diseases or injuries, and contraception (International Organization for Standardization, 2006).

1.4.2 HAIs associated with reusable medical devices

Medical devices can transmit infections to patients, healthcare workers, or visitors if the medical devices are not decontaminated appropriately before reuse. Authors of some reports have considered inadequate disinfection and sterilization practices as one of the critical factors causing high rates of HAIs in developing countries (WHO, 2011; Zaidi *et al.*, 2005).

Practically, it could be difficult to establish an association of an HAI with inadequately reprocessed medical devices. Reporting of HAIs associated with reusable medical devices is relatively poor globally and there have been few investigations on infections associated with reusable medical devices (Southworth, 2014). Southworth (2014) considers reluctance to publish failures as the possible reason for the small number of reports. Such reporting is even lower in developing countries where reuse of medical devices could be more common but less standardized and regulated.

However, a number of studies have reported HAIs associated with inadequate reprocessing of reusable medical devices. A microbiological survey carried out by Esel *et al.* (2002) in a university hospital in Turkey after an outbreak of *Serratia marcescens* mediastinitis in an intensive care unit showed inadequately decontaminated linens as the source of the outbreak. An investigation into a sudden increase in the SSI rate following ‘clean’ surgery in the UK showed that post-sterilization contamination of sets containing surgical instruments was linked to the increased rate (Dancer *et al.*, 2012). Tosh *et al.* (2011) conducted a case-control study to determine the source of seven SSIs that occurred after arthroscopic procedures at a hospital in Texas in 2009 and found that those SSIs caused by *Pseudomonas aeruginosa* were likely related to surgical instrument contamination with the bacteria during reprocessing. Studies from Italy and China reported hepatitis C virus (HCV) infections associated with

inadequately sterilized medical devices (Gaeta *et al.*, 1999; Lu *et al.*, 2012). Giri *et al.* (2013) reported that failure to maintain adequate disinfection and sterilization of surgical instruments might have led to a high rate of SSIs (23%) among patients who had undergone gastrointestinal surgery in a tertiary care hospital in Nepal.

About 1.3 million people die worldwide because of unsafe injections each year. Such deaths are mainly due to hepatitis B virus (HBV), HCV and human immunodeficiency virus (HIV). The issue of unsafe injections is even more traumatic in developing countries. An estimate has been made that persons in the developing world receive 1.5 injections per year, and half of such injections are considered "unsafe" (Sirnonsen *et al.*, 1999; WHO, 2015); such unsafe injections include injections with previously used syringe, needle or both without sterilization (Sirnonsen *et al.*, 1999). Syringes used for giving injections could be single-use disposable syringes or reusable syringes (usually glass syringes). Reusable (glass) syringes and needles need to be properly sterilized before their reuse. The IPEN Study Group (2012) reported that the use of glass syringes, compared with single-use disposable syringes, was consistently associated with unsafe injections (OR 8.4; 95% CI 6.4-10.9) and with the risk of blood-borne virus transmission (OR 12.2; 95% CI 9.7-15.5).

1.4.3 Sterilization of medical devices in healthcare facilities

Medical devices are decontaminated by cleaning, disinfection, sterilization, or a combination of these processes, depending on the device and the risk posed by its use (Spaulding's classification of medical devices according to the risk posed by their use is described in detail in Section 2.2). Critical devices such as surgical instruments come in contact with a normally sterile part of the body and pose a higher risk of infection to patients. Such devices are sterilized (normally after cleaning) using an appropriate sterilization technique before their reuse. Adequate sterilization kills or inactivates all forms of viable microorganisms including spores present on medical devices. Inadequate or ineffective sterilization of critical devices carries a risk of transmission of HAIs through person-to-person and environmental transmission of pathogens such as bacteria, fungi, viruses and prions (Rutala, Weber & Healthcare Infection Control Practices Advisory Committee, 2008).

Among the various chemical and physical methods of sterilization, moist-heat sterilization which uses steam under pressure as a means of killing microorganisms is considered the most robust and cost-effective method for sterilization of medical devices (Alfa, 2000; Rutala & Weber, 1999). This method of sterilization is also known as autoclaving and is the most widely used method for sterilization of medical devices.

Nowadays, minor surgical procedures are often performed in primary care facilities. Thorough attention to hand hygiene, appropriate use of personal protective equipment (PPE), a clean environment, and the use of sterile instruments should be given while preparing for these procedures (Clark, 2004). Cole (2007) mentions that the importance of infection control in primary healthcare facilities has increased in recent years. However, infection control practices, including decontamination practices, are poorly understood in primary healthcare facilities compared with higher level facilities (Cole, 2007). Considering the restricted availability of resources, the reuse of medical devices in developing countries may be higher than in developed countries (Shuman & Chenoweth, 2012). Therefore, understanding medical device decontamination practices in primary healthcare facilities in a developing country is more crucial. Studies in some countries including Brazil, the Netherlands and Norway indicate that reprocessing systems may not always function appropriately (Costa & Costa, 2012; Skaug *et al.*, 1999; Van Doornmalen & Dankert, 2005). The study in the Netherlands reported that about 60% of steam sterilizers used in Dutch hospitals and companies carrying out steam sterilization of medical devices could not meet the requirements the norms and standards related to technical condition, production processes and routine control tests (Van Doornmalen & Dankert, 2005).

1.4.4 Sterilization of medical devices in Nepal

Healthcare services are provided to the general public in Nepal through both public and private healthcare facilities. There are 102 public hospitals in the country providing primary, secondary and tertiary levels of hospital care. District-level hospitals and district hospitals provide primary level hospital care, whereas zonal hospitals provide secondary level hospital care (Starfield, 2001; WHO, 2007a). Healthcare services provided by these hospitals range from general healthcare services to specialized services relating to paediatrics, gynaecology, general surgery, general medicine, eye care, dermatology, orthopaedics, psychiatry and

dentistry (Department of Health Services - Ministry of Health and Population - Government of Nepal, 2015). Moist-heat sterilization (autoclaving) is likely to be used by all of these hospitals for sterilization of medical devices. However, medical device reprocessing in Nepal has not been well studied and the effectiveness of autoclaving in the hospitals in Nepal is unknown, despite the availability of indicators (biological and chemical) which can measure the effectiveness of a sterilization process carried out in a hospital.

In view of lack of sufficient resources, policies and country-specific evidence, patients in Nepal might be at higher risk of acquiring infections associated with inadequately reprocessed medical devices than the patients in developed countries. If the reasons for inadequate reprocessing were better understood, appropriate intervention strategies could be developed and implemented. This could reduce the load of HAIs in Nepal. Reducing the rate of such infections would improve the health of the population and ultimately reduce financial burden for the healthcare system of Nepal. Therefore, it is crucially important to investigate existing medical device reprocessing practices in primary and secondary care healthcare facilities (district-level, district and zonal hospitals) in Nepal and to formulate a way forward for the safe reuse of medical devices in these healthcare facilities. Such study can positively inform quality priorities for healthcare services in the region and may lead to a significant financial saving in healthcare in the future.

Higher level healthcare facilities, such as tertiary care hospitals, are generally expected to have better infrastructure and resources compared with the primary and secondary care hospitals (Ministry of Health and Population - Government of Nepal, 2014a; WHO, 2007a). Tertiary care hospitals could also be more likely to meet basic standards of medical device reprocessing compared with the lower level hospitals. Though it cannot be assured that all tertiary care hospitals in Nepal reprocess medical devices adequately, the need for investigating and improving medical device reprocessing in primary and secondary care hospitals is greater.

1.5 Healthcare Facilities in Nepal

Nepal is a land-locked country with a geographical area of 147,181 square kilometres. According to the most recent National Population and Housing Census 2011, Nepal has a

population of 26,494,504 (Central Bureau of Statistics - Government of Nepal, 2012). Until recently Nepal was divided into five development regions for administrative purposes; these development regions were further divided into 14 zones and 75 districts. However, the new constitution of Nepal came into effect on September 20, 2015. According to the new constitution, Nepal currently has a federal structure and has seven states. Each state further has local bodies including village institutions, municipalities and district assemblies (Constitutional Assembly Secretariat, 2015).

Currently, healthcare services are provided to the general public in Nepal through different types of healthcare service outlets including public and private healthcare facilities. Categories and numbers of public healthcare facilities are shown in Table 1.1 (Department of Health Services - Ministry of Health and Population - Government of Nepal, 2015). Some of the public healthcare facilities are being upgraded to higher level healthcare facilities. Therefore, the documented number of public healthcare facilities in the country varies to some extent from report to report. For the purpose of this study, the number of healthcare facilities identified in the annual report (2013/2014) of the Department of Health Services was used.

Sub-health posts, health posts, health centres and primary healthcare centres provide basic community-level healthcare services, whereas hospital-level healthcare is available starting from district-level hospitals/district hospitals to central hospitals. Each higher level service outlet works as the referral point for a lower level service outlet in the area, e.g. zonal hospitals are referral points for district hospitals (Department of Health Services - Ministry of Health and Population - Government of Nepal, 2015).

District hospitals and district-level hospitals are primary care hospitals (WHO, 2007a). These hospitals are the first line of service outlets providing hospital-level care including inpatient, outpatient, maternity, family planning, child health and emergency services. Zonal Hospitals provide specialized services equivalent to secondary-level care. Such specialized services are related to paediatrics, gynaecology, general surgery, general medicine, eye care, dermatology, orthopaedics and psychiatry. Central Hospitals provide sophisticated diagnostic and treatment facilities to provide speciality and super-speciality services (Department of Health Services - Ministry of Health and Population - Government of Nepal, 2015). The services provided by

regional and sub-regional hospitals are supposedly intermediate between zonal and central hospitals.

A major change in the healthcare system of the country is expected (at the time of writing this in 2018) as the country gradually implements its new constitution. Despite such change, the existing (i.e. 2018) system will be the foundation of the reformed healthcare system and current structures are expected to be utilized in some forms in the new system.

Table 1.1: Healthcare service outlets in Nepal

Healthcare service outlets	Number
Sub Health Posts (SHPs)	2247
Health Posts (HPs)	1559
Health Centres (HCs) / Primary Healthcare Centres (PHCs)	208
District-level Hospitals	16
District Hospitals	62
Zonal Hospitals	10
Sub-regional hospitals	3
Regional Hospitals	3
Central Hospitals	8

Source: Department of Health Services - Ministry of Health and Population - Government of Nepal (2015)

1.5.1 Emerging attention towards healthcare quality in Nepal

The Constitution of Nepal has considered quality healthcare as one of the 'basic needs of the citizens' and article 51 states the following policy relating to it:

> to ensure easy, convenient and equal access of all to quality health services (Constitutional Assembly Secretariat, 2015, p. 27)

The National Health Policy 2014 repeatedly emphasizes quality health services in its policies and strategies. The Government of Nepal considers 'providing access to quality health services to every citizen effectively' as one of its health policies (Ministry of Health and Population - Government of Nepal, 2014c).

The Ministry of Health and Population of Nepal issued a Policy on Quality Assurance in Health Care Services in 2007. Developing quality assurance as an integral part of the essential healthcare delivery system was one of the quality assurance policies mentioned in the document (Ministry of Health and Population - Government of Nepal, 2007).

Based on the National Health Policy 2014, the Ministry of Health and Population developed the Nepal Health Sector Strategy 2015-2020 (NHSS) for providing guidance to the health sector for the five years 2015 - 2020 (Ministry of Health and Population - Government of Nepal, 2015b). The NHSS was built on four strategic principles including equitable access to health services, quality health services, health system reform, and a multi-sectoral approach. The document further specified "improved quality of care at point-of-delivery" as one of the nine expected outcomes of the healthcare system in Nepal.

There is a clear emphasis on quality healthcare services in the policy documents issued by the government. Local empirical evidence in the area of healthcare quality is required for supporting the effective implementation of the policies.

The NHSS 2015-2020 and the Policy on Quality Assurance in Health Care Services 2007 mention infection prevention in the hospitals in Nepal (Ministry of Health and Population - Government of Nepal, 2007; Ministry of Health and Population - Government of Nepal, 2015b). The NHSS 2015-2020 mentions "improved infection prevention and healthcare waste management" as one of the outputs for achieving the outcome – "improved quality of care at point-of-delivery". Reviewing and enforcing standards for infection prevention are key interventions provided by the strategy document to achieve the expected outcome. The NHSS further considers the "percentage of infection rate among surgical cases" as one of the outcome-level indicators.

This study will provide information which could be crucially helpful in achieving the aforementioned outcome. Safe reprocessing of medical devices in healthcare facilities in Nepal is an important aspect of infection prevention.

1.6 Research Objectives

The research reported in this thesis has the following overall objectives: (i) to estimate the effectiveness of steam sterilization practices in primary and secondary care hospitals in Nepal, (ii) to understand compliance of these hospitals with standard steam sterilization practices, and (iii) to investigate the knowledge and attitudes of healthcare workers towards sterilization and reuse of medical devices.

The study has the following research objectives:

1. To understand the characteristics of primary and secondary care hospitals in relation to sterilization and reuse of medical devices
2. To investigate the knowledge and attitudes of healthcare workers towards sterilization and reuse of medical devices.
3. To explore routine practices for sterilization of medical devices in primary and secondary care hospitals in Nepal.
4. To determine the effectiveness of steam sterilization practices in primary and secondary care hospitals in Nepal.
5. To consider potential causes of steam sterilization failures in primary and secondary care hospitals in Nepal.
6. To determine the quality of water being used for cleaning and sterilization of medical devices in Nepal.
7. To provide recommendations for reducing the potential risk of HAIs from reuse of medical devices in Nepal.

1.7 Research Questions

This study will address the following key questions:

1. What are the differences in the characteristics of primary and secondary public hospitals in Nepal in terms of reprocessing and reuse of medical devices? *(relates to objective 1)*
2. Is there a significant difference in the level of knowledge, and attitudes towards sterilization and reuse of medical devices, between medical doctors, nurses, allied health workers and autoclave operators? *(relates to objective 2)*

3. What is the attitude of healthcare workers towards HIV positive individuals with regards to sterilization and reuse of medical devices? *(relates to objective 2)*
4. Do routine steam sterilization practices in these hospitals meet basic international/national standards of sterilization? *(relates to objective 3)*
5. What proportion of routine steam sterilization practices in these hospitals is effective in killing spores of *Geobacillus stearothermophilus* (biological indicators)? *(relates to objective 4)*
6. What proportion of routine steam sterilization practices in these hospitals produces acceptable results with class 5 chemical indicator tests? *(relates to objective 4)*
7. Do biological and chemical indicators produce comparable results while testing steam sterilization practices in these hospitals? *(relates to objective 4)*
8. What are the factors associated with steam sterilization failures in primary and secondary care hospitals in Nepal? *(relates to objective 5)*
9. What is the average pH and hardness of water being used for cleaning and steam sterilization of medical devices in these hospitals? *(relates to objective 6)*
10. What can be done to improve steam sterilization of medical devices in these hospitals? *(relates to objective 7)*

1.8 Thesis Organisation

This thesis begins with an introduction chapter (Chapter 1) where the background to the research is provided, HAIs are defined and their association with reusable medical devices is described. A brief introduction to healthcare facilities in Nepal is included in this chapter, Research objectives and research questions are also listed in this Chapter.

An introduction to medical devices, categories of medical devices and decontamination techniques are described in Chapter 2. The science of moist-heat (steam) sterilization of medical devices is elaborated in this chapter.

Chapter 3 provides a review of previous studies from different countries in the area of sterilization and reuse of medical devices. The review summarizes existing findings about the effectiveness of moist-heat sterilization, healthcare workers' knowledge and attitudes, staff

training, compliance with recommended practices, sterilization equipment, and the impact of HIV infection on medical device reprocessing.

Chapter 4 describes the research methods used for answering the research questions listed in Chapter 1. Sample design, sample size, sample selection, data collection tools and procedures, data management and analysis, and ethical considerations are discussed in this chapter.

The results of this study are presented in Chapters 5 to 8. The characteristics of the primary and secondary care hospitals included in this research are provided in Chapter 5. The results of effectiveness measurements of the steam sterilization cycles in the selected hospitals are presented in Chapter 6; factors associated with ineffective steam sterilization cycles are also presented in this chapter. Chapter 7 presents the findings of the audits of medical device reprocessing (with steam sterilization) practices. The results of a survey carried out to investigate the knowledge and attitudes of healthcare workers towards the sterilization and reuse of medical devices are detailed in Chapter 8. At the end of each result chapter (chapters 5 to 8), a section discussing the findings in the respective chapter is provided.

An overall discussion which brings together the research findings is provided in Chapter 9. Strengths and limitations of the study, implications of the findings, conclusions, and recommendations are included in this chapter.

CHAPTER 2. MEDICAL DEVICES IN HEALTHCARE AND THEIR REPROCESSING

This chapter defines medical devices and their categories depending on their clinical use. Microbial contamination of medical devices and methods of decontaminating them before reuse are explained. The level of sterility required for reusing medical devices is discussed with a focus on the moist-heat sterilization (autoclaving) process. An introduction to the medical device reprocessing cycle is provided and the role of water in medical device reprocessing is discussed. Also, a theoretical background to quality assurance of medical device reprocessing is presented.

2.1 Definition of Medical Devices

The Global Harmonization Task Force (2005, p. 5) has provided the following definition of medical devices:

> 'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:
>
> a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
>
> - diagnosis, prevention, monitoring, treatment or alleviation of disease,
> - diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
> - investigation, replacement, modification, or support of the anatomy or of a physiological process,
> - supporting or sustaining life,
> - control of conception,
> - disinfection of medical devices,
> - providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;
>
> and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

This definition has also been adopted by the International Organization for Standardization (ISO) and the WHO (ISO, 2006; WHO, 2003).

2.2 Reusable Medical Devices

Historically, most medical devices were typically made of metal and were in limited supply. Therefore, medical devices were primarily reusable. The materials, designs, and quantities of medical devices have evolved as a result of developments in material science and/or electronic technologies, and changes in medical/surgical practice (Malchesky *et al.*, 1995).

Currently, both disposable (single-use) and reusable (multiple-use) medical devices are in use. Single-use medical devices are meant to be disposed of safely immediately after use. However, the practice of reprocessing and reusing single-use medical devices exists across healthcare facilities worldwide, mostly in developing countries (Popp *et al.*, 2010). Such practice exists because of the high cost of replacing single-use medical devices and also the cost associated with the disposal of single-use medical devices (WHO, 2007b). The issue of reusing single-use medical devices is also under discussion because of environmental issues related to the disposal of a large amount of single-use medical devices globally (Kwakye *et al.*, 2010).There are also patient safety issues including infection control related to the reuse of single-use medical devices (Jayabalan, 1995; Popp *et al.*, 2010; Shuman & Chenoweth, 2012). In addition, techniques used for reprocessing medical devices can have adverse effects on the characteristics of single-use medical devices, for example, tensile strength of materials used in single-use medical devices can be affected by some reprocessing activities (Brown *et al.*, 2002).

This study primarily focusses on the sterilization and reuse of multiple-use medical devices, and all forthcoming discussions will be about reusable medical devices.

Spaulding (1968) classified reusable medical devices into three categories depending on the risk of infection associated with their use. Many national/international guidelines and standards use this classification of medical devices for recommending the level of decontamination required for reprocessing of medical devices. Decontamination processes recommended for medical devices of each of the following three categories, with a focus on decontamination of critical items, will be further discussed later in this chapter (sections 2.3, 2.4 and 2.5).

a. *Critical items:* Devices which come in contact with sterile parts of the body such as the vascular system, are categorized as critical items. Surgical devices, implants and endoscopes used in sterile body cavities are in this category. If critical items are not sterilized properly before reuse, there will be a risk of infection to the person on whom the item is used.

b. *Semi-critical items*: Semi-critical medical devices come in contact with mucous membranes or non-intact skin. These devices do not normally enter the sterile parts of the body. Examples of semi-critical devices include non-invasive flexible endoscopes, endotracheal tubes, inhalation therapy nebulizers and oral thermometers.

c. *Noncritical items:* Devices which are in contact with the intact skin of the human body are considered as noncritical items. Skin electrodes, blood pressure cuffs and stethoscopes are considered as non-critical items.

The ISO categorizes medical devices for the purpose of designating them to a product family. Medical devices are categorized based on their designs and material used. The material used in medical devices can be metal or non-metal and the design of the medical devices can be solid, hollow, pin and box joints, lumen, porous, tubing, moving parts, tortuous paths or lumen surrounded by a large mass (ISO, 2013). Medical devices can present a challenge to reprocessing depending upon their materials and design, for example, it could be difficult for a sterilizing agent to reach the interior of a medical device with tubing or tortuous paths.

2.2.1 Medical devices and microorganisms

Reusable medical devices possess bioburden (microbial contamination) on their surfaces after medical or surgical use. Studies have reported the level of bioburden on reusable medical devices after clinical use. Chan-Myers *et al.* (1997) found a bioburden level of 10 to 10^4 colony forming units (CFU) per device for lumened medical devices after clinical use. Lumened medical devices, such as sinuscopes, irrigation forceps and tissue extractors, have hollow tubular structures which are more difficult to clean than plain rigid surfaces. However, none of the medical devices contained bioburden levels greater than 10^4 after cleaning. A bioburden level of 0 to 4415 CFU per device was reported by Chu *et al.* (1999) for surgical instruments without lumens. Studies reported recovery of microorganisms including, but not limited to, *Staphylococcus* spp., *Micrococcus* spp., Diphtheroids, *Bacillu*s sp., Gram-negative rods, moulds and yeasts from medical devices before and after cleaning processes (Chan-Myers *et al.*, 1997; Chu *et al.*, 1999; Pinto *et al.*, 2010; Rutala *et al.*, 1998; Saito *et al.*, 2014). de Souza Evangelista *et al.* (2015) recovered coagulase-negative staphylococci, *Escherichia coli*, *Pseudomonas* spp, *Stenotrophomonas maltophilia*, *Acinetobacter baumannii* complex, *Cladosporium* spp, *Aspergillus* spp, and *Candida* spp from surgical instruments after clinical use. The authors considered the skin of patients and healthcare workers, surgical sites, air and cleaning solutions to be the probable sources of microorganisms.

However, these studies were unlikely to detect all microorganisms present on the medical devices because the determination of microbial load in these studies was carried out merely by culturing the microorganisms. Some microorganisms cannot be detected by routine microbiological culture methods and may require other methods such as molecular techniques for their detection. None of the above studies were designed to detect viruses and prions, and they were also unlikely to detect some of biofilm-forming microorganisms. Some of them, for example the study by Saito *et al.* (2014), performed only aerobic culture and could not detect anaerobic bacteria. Therefore, the actual level of bioburden on reusable medical devices is likely to be greater than the reported level.

2.2.1.1 Biofilms

The formation of a biofilm on rigid surfaces has made the association of microorganisms with medical devices more complex. Biofilm is an accumulation of microorganisms which is irreversibly attached to a surface with the formation of an extracellular polymeric substance (EPS) matrix. The matrix is primarily made up of polysaccharide material along with non-cellular substances including mineral crystals, clay/silt particles, corrosion particles, or blood/tissue components. Microorganisms in a biofilm are phenotypically different from their planktonic (free-floating) counterparts (Donlan, 2002). The formation of a biofilm is a complex, multi-step process, comprising surface conditioning, attachment, colonization, and detachment (Lindsay & Von Holy, 2006). However, specific conditions including the presence of colonizing microorganisms, appropriate surface, adequate nutrients, moisture, appropriate temperature conditions and sufficient time are required for the formation of the biofilm (Roberts, 2013).

Biofilm has great public health significance because of its role in some infections, including device-associated infections. Microorganisms in biofilms have lowered metabolic rates, are more difficult to remove by routine cleaning procedures, and more resistant to antimicrobial agents compared to planktonic cells. Formation of biofilm may occur on reusable medical devices if they are not cleaned and reprocessed promptly after use. Medical devices with lumens are more prone to biofilm formation if they are not processed according to standard reprocessing protocols (Roberts, 2013).

2.2.1.2 Prions

In addition to bacteria, fungi, viruses and protozoa, other proteinaceous substances are also present on used medical devices (Cloutman-Green *et al.*, 2015). Prions, one of such proteinaceous substances, are infectious but lack nucleic acid (Prusiner, 1998). Prions cause fatal degenerative brain diseases known as transmissible spongiform encephalopathies (TSEs) or prion diseases. Prions are primarily found in brain tissue but may also exist in other organs, such as the spleen, tonsils and lymph nodes. Creutzfeldt-Jakob disease (CJD) is the most common type of prion disease occurring in human beings (Secker, Hervé & Keevil, 2011). Though CJDs mostly occur sporadically, iatrogenic CJDs associated with reusable

surgical instruments, allografts, hormonal extracts or blood components have also been reported (Brown *et al.*, 2012). One important feature of prions relevant to the reprocessing of medical devices is that they are resistant to conventional physical and chemical methods of disinfection and sterilization. Some recommendations are available for sterilizing prion-contaminated medical devices (Rutala & Weber, 2010).

2.2.1.3 Inactivation or killing of microorganisms

Microogranisms differ in their abilities to resist inactivation or killing by different agents or processes (Russell, 1998). In general, prions are the most resistant to inactivation or killing whereas enveloped viruses are the least resistant. After prions, bacterial spores are the second most resistant to killing processes (Table 2.1). However, the resistance of microorganisms can vary depending on the nature of the killing/inactivation agent and the species involved (Russell, 1998).

2.3 Decontamination of Medical Devices

The key objective of reprocessing medical devices is to remove or kill microorganisms contaminating medical devices and make the devices safe for further reuse. The process of removing or killing microorganisms present on objects is known as ‘decontamination’.

Decontamination makes objects safe for handling, reuse, or disposal (Rutala *et al.*, 2008). Cleaning, disinfection and sterilization are the processes which can decontaminate medical devices. However, the level of decontamination varies depending on the process used. In practice, such processes are used in combination to decontaminate used medical devices. The three decontamination processes are commonly defined as follows:

Table 2.1: Resistance of microorganisms to inactivation in descending order

Microorganisms		Examples
Prions	**RESISTANT**	Creutzfeldt-Jakob Disease
Bacterial spores		*Bacillus* spp.
Protozoal cysts/helminth eggs		*Cryptosporidium spp.*
Mycobacteria		*M. tuberculosis, M. terrae*
Non-lipid or small viruses		Poliovirus, papilloma viruses
Fungal spores		*Aspergillus* spp., *Penicillium* spp.
Gram negative bacteria		*Pseudomonas* spp., *Escherichia* spp
Vegetative fungi		*Aspergillus* spp., *Candida* spp.
Vegetative helminths and protozoa		*Cryptosporidium* spp., *Giardia* spp.
Large, non-eveloped viruses		Adenoviruses, rotaviruses
Gram positive bacteria		*Staphylococcus* spp., *Enterococcus* spp.
Enveloped viruses	**SUSCEPTIBLE**	HIV, HBV

Adapted from McDonnell and Sheard (2012)

a. *Cleaning:* Cleaning is the process of physically removing soils, such as blood, body fluids, tissues, excretions and foreign materials, from the used medical devices by means of physical and/or other methods such as use of detergents (WHO, 2016a).

b. *Disinfection:* Disinfection kills or removes the microorganisms, but not necessarily the bacterial spores, present on the medical devices to a level which is not harmful to health. An upper level of disinfection, known as high-level disinfection (HLD), is used for decontaminating some medical devices which cannot withstand a sterilization process; HLD kills all microorganisms present on the medical devices except a small number of spores (Spaulding, 1968; WHO, 2016a).

c. *Sterilization:* The validated process of making a medical device or a product free from any viable microorganisms is known as sterilization (ISO, 2006).

The level of decontamination required for reprocessing of a medical device normally depends on the risk of infection posed by its use. Recommendations for the levels of decontamination required for the used medical devices are made based on the Spaulding's classification of medical devices (Table 2.2).

This study focusses on the reprocessing of critical medical devices. Therefore, sterilization will be discussed in detail in the following sections.

2.4 Sterilization

Sterility is the "state of being free from viable microorganisms", although absolute sterility of medical devices cannot be guaranteed. Sterility of medical devices is theoretically explained in terms of the probability of finding a viable microorganism on a sterilized medical device (ISO, 2006). This probability is commonly known as "Sterility Assurance Level (SAL)".

Table 2.2: Recommended decontamination levels according to risk categories of medical devices

Risk category	Examples	Recommended decontamination level
Critical (high)	Implants, surgical instruments, dental hand pieces	Sterilization
Semi-critical (intermediate)	Flexible endoscopes, oral thermometer, inhalation therapy nebulizers	Disinfection (high-level)
Non-critical (low)	Stethoscope, skin electrodes, blood pressure cuffs	Cleaning

Source: Spaulding (1968)

When a population of microorganisms (also known as bioburden) is exposed to a killing process for a particular period of time, the population reduces by 90%, which is one-log reduction in the number of microorganisms. If the logarithm of number of microorganisms is plotted on a graph against the exposure time, microbial death follows a straight line (Figure 2.1). A six log reduction is needed to reduce one million (10^6) microorganisms to one. Additional six log reduction is required to reduce the number of microorganisms to 10^{-6}. Therefore, a 12 log reduction is required to reduce one million microorganisms to 10^{-6}. Reducing the number of microorganisms to 10^{-6} means that the probability of finding a single viable microorganism is one in a million (10^{-6}). This probability is used in healthcare settings as a SAL of 10^{-6} (ISO, 2006; McDonnell & Sheard, 2012; Mosley, 2008). The time required for a particular killing method to reduce the number of microorganisms by one log is known as the decimal reduction value i.e. D-value (Mosley, 2008). If the D-value of a microorganism for a particular process is 1 min , the time required for achieving SAL of 10^{-6} will be 12 min i.e. items need to be exposed to that process for a time period of 12 min. This is the 'holding period' or 'exposure period' required for achieving an SAL of 10^{-6}. Spores are the most resistant form of viable microorganisms and they have higher D-values. The D-values of spores, for example spores of *Geobacillus stearothermophilus*, are commonly used for determining an exposure or a holding period for a sterilization process (ISO, 2006; ISO, 2009; von Woedtke & Kramer, 2008). Using such resistant microorganisms for qualifying a sterilization process encompasses all other microorganisms, including pathogenic

microorganisms, which are less resistant to the process. Spores are also used in biological indicators (Section 4.2.1), which are commonly used for determining the effectiveness of a sterilization process.

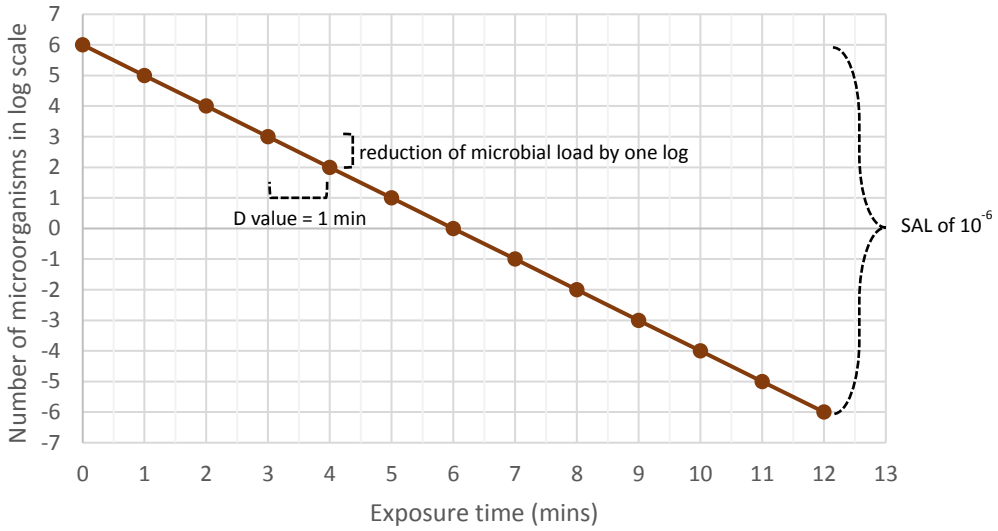

Figure 2.1: Logarithmic reduction of a microbial load during a sterilization process
[graph plotted according to the theoretical example provided by Perkins (1956, p. 35)]

Medical devices can be sterilized by chemical, physical or irradiation methods. One of the physical methods of sterilization is heat, which can be used in different forms such as steam, flames or dry air. Sterilization using steam as a sterilising agent is known as moist-heat sterilization or autoclaving.

2.4.1 Moist-heat sterilization (autoclaving)

The process of sterilization which uses steam under pressure is known as autoclaving and the equipment which is used to carry out this process is known as an autoclave. The word "autoclave" is derived from the French '*auto'* (self) and Latin *'clavis'* (key) and refers to the self-locking pressure vessel (Online Etymology Dictionary, 2017). Autoclaving is the most widely used method for sterilization (Allen, Humphreys & Sims-Williams, 1997; Coulter *et al.*, 2001; Matsuda, Grinbaum & Davidowicz, 2011) and is considered the most robust and cost-effective method for sterilization of medical devices (Alfa, 2000; Rutala & Weber, 1999).

Autoclaving is based on the principle that the boiling point of water increases by increasing the pressure of a boiling chamber. If water is boiled under high pressure, steam with high temperature is produced. Water requires a good amount of heat when it changes its state from liquid to gas. Such heat required for evaporation of water is known as "latent heat of vaporization of water" which is about 2200 kJ/kg at 121°C. For sterilization, medical devices are exposed to steam with high temperature and pressure. When steam comes in contact with the cooler surfaces of medical devices, it condenses and releases thermal energy (i.e. latent heat of vaporization). The released thermal energy will coagulate microbial protein and kill microorganisms. In addition, the condensation of steam creates negative pressure on the surfaces and draws more steam towards the object to be sterilized (McDonnell & Sheard, 2012; Van Doornmalen & Kopinga, 2008). However, the sterilization process will only be effective when all surfaces of the medical devices to be sterilized come into contact with the steam. The sterilization chamber (autoclave chamber) is occupied with atmospheric air (also known as dry air as it has low moisture content) prior to a sterilization cycle. If the dry air cannot be removed from the autoclave chamber prior to the sterilization cycle, it will prevent the steam from coming into contact with the surfaces of the medical devices. This interference of the dry air may lead to incomplete sterilization. Therefore, effective sterilization requires the atmospheric air to be eliminated from the sterilization chamber (Lee & Bishop, 2013).

2.4.1.1 Moist-heat sterilization cycle

An autoclave cycle (also known as moist-heat sterilization or steam sterilization cycle) has three phases: conditioning, exposure (holding period) and post exposure (Figure 2.2). The conditioning phase comprises the period of the sterilization cycle before the temperature and the pressure required for sterilization are reached. This phase encompasses generation of the steam and displacement of the air by the steam in the sterilization chamber. At the end of the phase, controlled environmental conditions are achieved in the sterilization chamber including the medical devices to be sterilized (Hancock, 1997). During the holding period or the exposure phase, the achieved conditions are maintained in the sterilization chamber for a pre-determined period of time and medical devices are exposed to those conditions. Minimum required holding periods have been established and recommended for different temperatures (Table 2.3). Indeed, these are the absolute minimum requirements and the times

recommended do not include the additional time required for achieving the direct exposure of all the surfaces of medical devices to saturated steam for effective sterilization. Therefore, the actual holding period required for an effective sterilization may differ from these minimum requirements, for example, Rutala *et al.* (2008) recommend an exposure time of 30 min for sterilizing wrapped medical devices in a gravity displacement autoclave (Section 2.4.1.2).

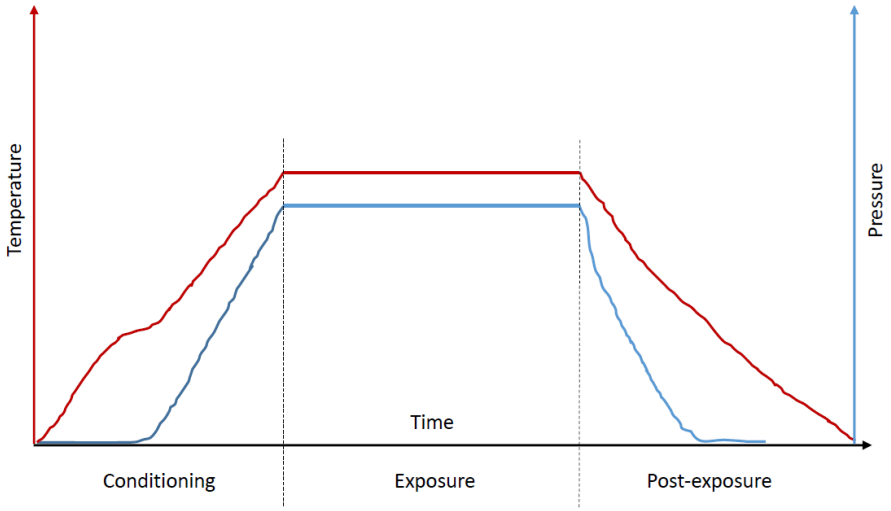

Figure 2.2: Three phases of a typical steam sterilization cycle
Source: ISO 17665-1:2006 E

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The post-exposure period is the last stage in which post-vacuuming (for drying sterilized packages) and/or cooling of the medical devices is carried out, and the pressure of the sterilization chamber is brought back to atmospheric level. For post-vacuuming, steam is forcefully expelled from the autoclave so that the pressure inside the autoclave decreases to below atmospheric level; because of the reduced pressure, the moisture inside the sterilized packages gets evaporated leaving the packages dry. However, not all autoclave cycles have a post-vacuuming phase.

Table 2.3: Minimum exposure times for different sterilization temperatures

Temperature	Time
121°C	15 min
126°C	10 min
134°C	3 min

Source: ISO/TS 17665-2:2009(E)

2.4.1.2 *Types of autoclaves*

The following designs of autoclaves are commonly described in the literature, depending on the method used for displacing dry air with saturated steam in the sterilization chamber.

Basic pressure-cooker type autoclaves

These are basic forms of autoclaves, with a sterilization chamber, the bottom part of which is filled with water. The water can be heated with a built-in electric heating system or any other source of heat such as a gas stove. These autoclaves are fitted with basic structures such as a pressure gauge, safety valve, pressure control valve, air removal valve and water release valve. These autoclaves usually have a small portable size (for example, a table top autoclave having a capacity of less than 2 cubic feet), however, some of them have larger capacities (Huys, 2010). When water in the chamber is heated up, formation of steam takes place gradually. The steam generated gradually dilutes the air in the chamber and the mixture of air and steam is slowly vented though the air removal valve. Once the mixture of steam and air is completely removed from the chamber, the air removal valve is closed and only steam remains in the chamber. Hancock (1997) has named this process of air removal from the autoclave chamber the ‘dilution technique’. The closed chamber is gradually heated up till the required pressure is attained. The pressure is maintained for the exposure period required to sterilize the medical devices in the chamber. This technique of autoclaving has only poor air

removal ability. Therefore, autoclaves using this technique are not recommended for sterilizing wrapped packages of medical devices, porous loads, or medical devices having lumens or complex tortuous paths (WHO, 2016a).

Gravity displacement autoclaves

Gravity displacement autoclaves have a chamber for sterilizing medical devices and a separate source of steam external to the chamber. In addition, these autoclaves are normally equipped with piping systems, an air venting system, a control system and gauges (McDonnell & Sheard, 2012). The piping system helps in the conditioning, sterilization and cooling/drying phases of the autoclave cycle. The steam is generated in a separate boiler (for some autoclaves, the boiling compartment is separate but permanently connected to the sterilization chamber) and admitted to the sterilizing chamber near or at the top. The steam accumulates at the top of the sterilization chamber, as the steam is lighter than the air. As the volume of the steam increases at the top of the chamber, the air gradually gets displaced downward into the drain system and the chamber ultimately fills with the saturated steam (Hancock, 1997). However, these autoclaves are still not considered very good for complete air removal from the sterilization chamber and are not recommended for wrapped packages, porous loads and medical devices with lumens and tortuous paths (Rutala *et al.*, 2008; WHO, 2016a).

Pre-vacuum autoclaves

Pre-vacuum autoclaves use an external driving force to expel dry air from the sterilization chamber before admitting steam into the chamber. This process of removing air from the chamber is also known as ‘dynamic air removal’ (Hancock, 1997). Because of their better air removal capabilities compared to the autoclaves discussed above, these autoclaves are recommended for sterilizing wrapped packages, porous loads and lumens (Rutala *et al.*, 2008; WHO, 2016a).

For further improving the air removal capabilities of some autoclaves, several steam pulses are generated in the sterilization chamber during the initial phase of the autoclave cycle. Steam pulses are generated by pressurizing and depressurizing the sterilization chamber alternatively. The steam pulsing may occur only above atmospheric pressure, only below

atmospheric pressure or both above and below atmospheric pressure (Hancock, 1997; Huys, 2010). The below-atmospheric steam pulsing is also known as 'fractioned-prevacuum' which utilizes advantages of both the pre-vacuuming and steam pulsing. Sterilization cycles with the fractioned pre-vacuum are considered the safest sterilization process for porous loads, wrapped packages and complex medical devices (Huys, 2010).

2.5 Medical Device Reprocessing Cycle

The reprocessing of medical devices comprises a set of processes which make a previously used medical device ready for its subsequent use (WHO, 2016a). Such processes typically include transport of used devices, cleaning and/or disinfection, inspection, packaging, sterilization, transport of sterile packages, storage and use (Figure 2.3). A dirty to clean work flow needs to be maintained when accomplishing these processes in order to avoid contamination.

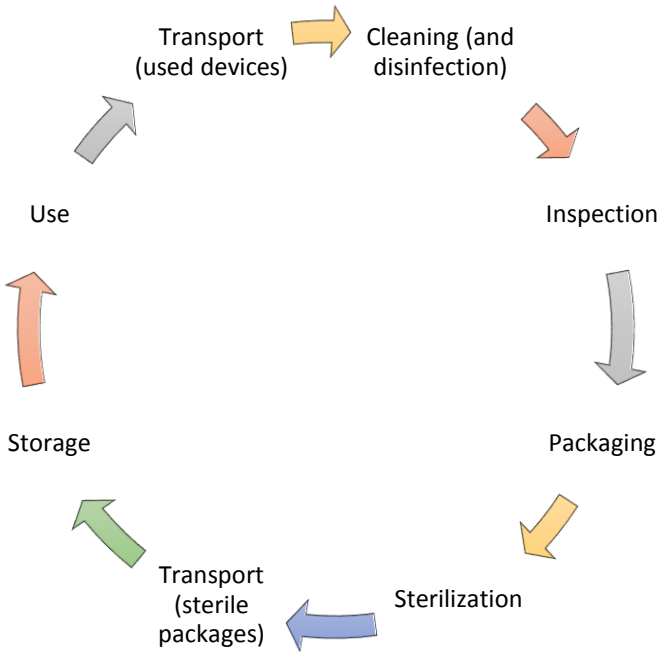

Figure 2.3: Medical device reprocessing cycle for a critical medical device
[source: Huys (2010) and WHO (2016a)]

Transport: Used medical devices are transported to a reprocessing area using strong, leak-proof and puncture-proof containers covered with a lid.

Cleaning (and disinfection): Medical devices become soiled with organic and inorganic materials from patients, or with the materials used during a clinical procedure (for example, gels, lubricants and cement). During the cleaning process, such soils are removed from used medical devices, using water and other cleaning agents. Cleaning prior to sterilization has a crucial role in reprocessing of medical devices as it removes most of the microorganisms (bioburden) from the devices. For a sterilization process to be effective, there should be sufficiently low bioburden on the medical devices prior to sterilization (Swenson, 2012). Initial reduction of microorganisms by cleaning process determines the achievement of SAL of 10^{-6} (Lee & Bishop, 2013). Cleaning enhances contact of the medical device surfaces with sterilizing agents used for killing microorganisms. In addition, cleaning also prevents inactivation of such agents by the soils present on the medical devices (McDonnell & Sheard, 2012), and cleaning of medical devices can also minimize corrosion of medical devices (Huys, 2010). In some healthcare facilities, used medical devices are pre-disinfected with a disinfectant (for example with calcium or sodium hypochlorite solution) before cleaning, to make them safe for subsequent handling by the staff involved in reprocessing the medical devices (Huys, 2010). Medical devices can be cleaned manually or by using automated methods such as using a washer-disinfector. In resource-poor settings, manual methods are most likely to be used, as they are cheaper and can be performed by less qualified individuals. Some medical devices, including lumened instruments, electric devices and other delicate devices need to be cleaned according to the manufacturer's instructions. In general, medical devices are opened and/or disassembled prior to cleaning so that all surfaces of the devices get exposed to the cleaning process (McDonnell & Sheard, 2012). A manual cleaning process can include multiple steps such as pre-rinsing, washing (usually with a chemical agent and brushes) and rinsing. After cleaning, medical devices are dried using non-linting towels. Staff involved in the cleaning of used medical devices should use PPE to minimize microbiological, chemical and physical hazards (McDonnell & Sheard, 2012). The equipment recommended for use while cleaning medical devices includes face-protection, a water-proof gown, heavy duty gloves, closed footwear and a head cover.

Inspection: Medical devices are inspected for cleanliness and functionality after cleaning (Reichert, 1997). Inspection for cleanliness is visual, often with the help of a magnifier. However, at present, tests for assessing the effectiveness of cleaning processes are also available (McDonnell & Sheard, 2012). Such tests detect protein, adenosine triphosphate (ATP) or haemoglobin present on the surface of medical devices. Usually, samples for these

tests are obtained by swabbing the surfaces of cleaned medical devices and then subjecting the swabs to biochemical analyses. Different test kits are commercially available for carrying out these tests routinely in healthcare facilities (McDonnell & Sheard, 2012). Medical devices are also tested for functionality after the cleaning process, to ensure that the devices perform as expected. Disassembled medical devices are re-assembled for functionality testing.

Packaging: Reusable medical devices are packaged in wraps (e.g. textiles), pouches or rigid containers before sterilizing them using a sterilization technique. Medical devices can be packaged using one of these packaging systems or a combination of two or more of these systems (ISO, 2013). Traditionally, medical devices are packaged in two separate layers of wrapping materials; the outer layer for handling and transportation of sterile packages and the inner layer for aseptic presentation of the devices during a procedure (McDonnell & Sheard, 2012). Packaging systems must allow a sterilizing agent to enter into the packages, allow the drying, aeration and dissipation of the sterilizing agent, provide a barrier to the microorganisms to maintain sterility of packages and facilitate the aseptic presentation of the sterilized devices while using them with patients (Gorman-Annis, 1997).

Sterilization: Packages of medical devices are loaded in a sterilizer and are sterilized following a validated sterilization process. Medical devices packages are loaded in the sterilizer in such a way that the sterilizing agent can reach all surfaces of the medical devices to be sterilized. Then the sterilizer is operated for a specified period of time under specified conditions to kill microorganisms. Effectiveness of a sterilization process can be measured using different chemical or biological indicators (Section 4.2.1). Sterilization using moist-heat has been described in detail in Section 2.4.1.

Transport of sterile packages: Sterilized packages of medical devices are transported to the storage area in such a way that recontamination of packages is prevented and sterility of the packages is maintained. Dedicated closed trolleys or container systems are usually used for transporting sterile packages to the storage area.

Storage: Sterile packages of medical devices are stored in a restricted and dedicated area which is dry, well-ventilated and dust-free. The storage area is physically separated from the rest of the reprocessing area. Moderate temperatures (18 - 22°C) and relative humidity (35 -

50%) need to be maintained in the storage area (McDonnell & Sheard, 2012). Packages need to be stored in such a way that first entered packages are removed first from the storage area.

Use: Safe use of sterilized medical devices on a patient is the ultimate goal of a reprocessing system. At the point of use, sterilized medical devices should be handled and used correctly considering the concept of aseptic procedures. Inadequate handling at the point of use can make the whole reprocessing cycle worthless.

2.5.1 Water for reprocessing of medical devices

Water has an important role in the reprocessing of medical devices. Water is primarily used during the cleaning and sterilization (steam) processes of the reprocessing cycle. Use of water during the cleaning process can be for maintaining moistness of used medical devices, rinsing organic soils from medical devices, preparing cleaning chemistries (detergents) and final rinsing of medical devices. On the other hand, use of water during the moist-heat sterilization process is mainly for generating steam.

Quality of water is generally defined in terms of its physical and chemical characteristics. pH and hardness are two important qualities of water. The pH of water specifies its acidity or alkalinity whereas the hardness of water is determined by the levels of calcium and magnesium ions present in the water. However, other chemicals and contaminants also determine the quality of water. Poor water quality can cause corrosion of devices, hard-water deposits on devices, pitting of instruments, inactivation of detergents (and thus inadequate cleaning of devices), pyrogenic reactions due to endotoxins and other pyrogenic agents, and infections due to microbial contamination (Klacik, 2015). Production of good quality steam is critical while sterilizing medical devices using moist-heat. Saturated steam is most effective in sterilizing medical devices whereas superheated steam, wet steam (also known as supersaturated steam) and steam containing non-condensable gases are not good for this purpose. A good quality saturated steam can only be obtained if good quality water is used for generating steam.

Guidelines and standards have made recommendations about the qualities of water required for reprocessing medical devices. The recommended pH of water for cleaning of medical

devices is between 6 and 9 (Lyon, 2008; McDonnell & Sheard, 2012), and a total hardness level of less than 150 mg $CaCo_3$/L is normally considered as the required level of hardness for cleaning of medical devices (Lyon, 2008; McDonnell & Sheard, 2012; Standards Australia & Standards New Zealand, 2014). For the purpose of generating steam for sterilization, only treated water (by reverse osmosis, deionization or distillation) has been considered as appropriate water (Department of Health-UK, 2016) .

The relationship between poor quality water and decontamination processes has not been well studied and documented. Many places, particularly in developing countries, may not have a system for treating drinking water. Water available in such places might not be suitable for the cleaning and sterilization of medical devices. Ineffective cleaning may damage the sterilization process. Sources of drinking water in Nepal vary among municipalities and villages. Water with different qualities might have different impacts on the reprocessing of medical devices.

2.6 Assuring Quality of Medical Device Reprocessing (A Theoretical Background)

Reprocessing of medical devices is associated with quality and safety in healthcare. Therefore, theoretical/conceptual frameworks for quality and patient safety in healthcare can be helpful also in understanding quality management/assurance in medical devices reprocessing.

As described by Eggli and Halfon (2003), most of the quality assurance/improvement frameworks revolve around four basic entities of quality management: resources (human and other resources); activities (processes); patients (clients) and effects (products).

Donabedian (1988) has described a ‘Structure-Process-Outcome’ model for assessing the quality of care in healthcare facilities. According to him, this model is appropriate in a situation where good structure increases the possibility of good process, and good process increases the possibility of a good outcome.

Carayon *et al.* (2006) described a work system design for patient safety known as the 'Systems Engineering Initiative for Patient Safety (SEIPS)' model. The model was nested in Donabedian's quality model by integrating human factors within it. According to the model, the person, tasks, tools and technologies, physical environment, and organizational conditions of a work system interact with each other, influence each other and produce different outcomes.

International Standards Organization (ISO) Quality Management Systems have been applied to different sections of health care (e.g., radiology and laboratories) globally. These systems also include additional areas of quality management such as management, measurement, analysis and ongoing improvement (Australian Standard & New Zealand Standard, 2006).

ISO uses a process-based quality management system which is based on principles of customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision making and mutually beneficial supplier relationships. ISO believes that desired results can be achieved more efficiently when activities and related resources are managed as a process. ISO further states "identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives" (Australian Standard & New Zealand Standard, 2006, p. iv; Australian Standard & New Zealand Standard, 2008). Klosz (2008) and Niel-Lainé *et al.* (2011) have described the use of the ISO's "process model" for quality management of sterilization services.

According to Wachter (2012), the modern approach to patient safety is based on "system thinking" rather than the "blame and shame game". "System thinking" admits that humans make mistakes. It believes that safety depends on creating systems which prevent or catch errors before they cause harm. Vincent, Taylor-Adams and Stanhope (1998) categorized root causes of errors under different factors including institutional context, organization and management, work environment, team, individual staff member, task, and patient.

From the theories described above, it is clear that ensuring the quality of medical device reprocessing is not dependent on a single process or entity, but rather quality in reprocessing can only be achieved if different core processes (transport, cleaning, inspection, packaging, sterilization, storage and use), support processes (such as human resources, technical

resources, purchasing, documentation and quality assurance) and management processes (such as planning, review, resource management, risk management and continual improvement) function together effectively. In light of these theories, the objectives of this study (Section 1.6) were developed and the data obtained have been analysed and discussed.

CHAPTER 3. SUMMARY OF EXISTING EVIDENCE

This chapter summarizes the findings of previous studies from Nepal and other countries on the effectiveness of moist-heat sterilization, factors associated with the effectiveness of moist-heat sterilization, healthcare workers' knowledge and attitudes about sterilization and disinfection, training of healthcare workers, compliance of healthcare facilities with recommended sterilization practices, and equipment used for moist-heat sterilization.

3.1 Effectiveness of Moist-heat Sterilization (Autoclaving)

The effectiveness of moist-heat sterilization practices in healthcare facilities can be assessed using chemical or biological indicators (Section 4.2.1). Biological indicators are considered the 'Gold Standard' for monitoring the effectiveness of moist-heat sterilization practices.

Studies on the effectiveness of steam sterilization practices were sought from the Google Scholar, MEDLINE and CINAHL databases, using the keywords: 'infection control', 'sterilization', 'decontamination', 'disinfection', 'autoclave', 'hospital', 'healthcare', 'medical devices', 'reuse', 'patient safety', 'reprocessing', and 'monitoring'. Bibliographies from the retrieved articles were used to identify further relevant publications.
Only original studies (i.e. not reviews or guidelines) published after 1980 in English, which used biological indicators to test sterility and included detailed information about methods (sample size, type of hospital studied) and results (sterilization failure rates) were reviewed.

A small number of studies using biological indicators to assess the effectiveness of moist-heat sterilization practices was found from different countries. Most of the studies used spores of *G. stearothermophilus* as an indicator for measuring the effectiveness of sterilization; however, others used a mixture of *G. stearothermophilus* and *Bacillus subtilis* spores (Messieha, Rosen & Beck, 1989; Patiño-Marín *et al.*, 2015). Also, the number of spores contained in the biological indicator units used was not reported by most of the studies. The number of autoclave cycles tested varied considerably between studies, ranging from 22 to 2437 autoclave cycles (Acosta-Gío *et al.*, 2002; Skaug, 1983). Neither the sample sizes nor the number of cycles for studies were calculated following robust methods.

Table 3.1: Summary of studies using biological indicators to assess the effectiveness of steam sterilization

Author (year)	Country	Type of healthcare facilities	Autoclave failure proportion	Remarks
Skaug (1983)	Norway	Oral Surgeries	22.7%	Oral surgeons were provided with biological indicator (BI) units and instructions to use them. Altogether, 22 autoclaves were tested twice using 4 biological indicator units for each sterilization cycle.
Palenik *et al.* (1986)	US	Endodontic Offices	6.1%	Practitioners were provided with two biological indicator strips and instructions for using them. Altogether, 66 autoclaves were tested twice using one indicator strip for each sterilization cycle.
Scheutz and Reinholdt (1988)	Denmark	Dental Offices	4.5%	Each dental practice was provided with five biological indicator units. Altogether, 314 dental offices tested their autoclaves five times using the indicators provided.
Messieha *et al.* (1989)	Ohio, US	Dental Offices	43.0%	Dental practitioners were provided with two biological indicator strips (each containing 1.3-1.6 x 10^6 spores of *B. subtilis* and 1.3-1.6 x 10^5 spores of *G. stearothermophilus*) and instructions for using them. Altogether, 194 autoclaves were tested once using the indicators provided.
McErlane, Rosebush and Waterfield (1992)	Canada	Dental Offices	2.3%	Dental offices were provided with 24 biological indicator strips (each containing 1.2-2.2 x 10^4 spores of *B. stearothermophilus* and 1.3-2.1 x 10^6 spores of *B. subtilis*) and instructions for using them. In total, 502 dental offices participated in the study and tested 1,190 autoclave cycles with the indicators provided during a period of one year.
Burke *et al.* (1998)	UK	Dental Practices	1.5%	Dental practitioners were provided with three biological indicator strips and instructions for using them. In total, 401 practices tested their autoclaves twice using the indicators provided.
Skaug *et al.* (1999)	Norway	Dental Offices/ Clinics	8.8% (1985) 1.8% (1996)	In the 1985 study, practitioners were provided with four biological indicator units and instructions; altogether, 212 autoclaves were tested once using the indicators provided. In the 1996 study, practitioners were provided with two sets of three biological indicator units (each containing 3.2 x 10^5 spores of *G. stearothermophilus*) and instructions; in total, 163 autoclaves were tested twice with the indicators provided.

Table 3.1 continues to next page

Table 3.1 continues from previous page

Table 3.2: Summary of studies using biological indicators to assess the effectiveness of steam sterilization

Author (year)	Country	Type of healthcare facilities	Autoclave failure proportion	Remarks
Coulter *et al.* (2001)	England and Wales, UK	Primary Care Practices	2.0%	Practitioners were provided with three biological indicator ampoules and instructions for using them. In total, 302 autoclaves were tested twice with the indicators provided.
Acosta-Gío *et al.* (2002)	Mexico city	Dental Offices	6.7%	Practitioners were provided with biological indicator strips (each containing 10^5 spores of *G. stearothermophilus* and 1.7 x 10^6 spores *B. subtilis*) and trained in using them. In total, 61 dental offices tested 2437 autoclave cycles.
Kelkar, Bal and Kulkarni (2004)	India	Eye Care Hospitals	12.0%	Eleven eye hospitals were supplied with biological indicator strips (each containing 10^5 spores *G. stearothermophilus)*; however, it has not been made clear about the person performing the autoclave testing. The autoclaves in the hospitals were tested once each month during a period of one year. Altogether, 125 autoclave cycles were tested.
Healy *et al.* (2004)	Ireland	Dental Practices	11.3%	Practitioners were provided with three biological indicator units and instructions for using them. In total, 265 autoclaves were tested twice with the indicators provided.
Wai-Kwok and Chi-Ming (2007)	Hong Kong	Private Dental Practices	7.0%	Practitioners were provided with two biological indicator ampoules and instructions for using them. In total, 175 autoclaves were tested once with the indicators provided.
Miranzadeh *et al.* (2013)	Kashan, Iran	Government hospitals	2.9%	Autoclaves in six government hospitals were tested with biological indicator once a week for 52 weeks. It is not clear whether operators or the researcher tested the autoclaves. Altogether, 312 autoclave cycles were tested.
Okemwa, Kibosia and Nyamagoba (2014)	Western part of Kenya	Dental Clinics	31.0%	Clinics were provided with biological indicator units and instructions for using them. Altogether, 29 sterilizers were tested once. However, two of the sterilizers used sterilization technique other than autoclaving. Failure proportion specific to the autoclaves was not provided.
Patiño-Marín *et al.* (2015)	Mexico	Dental Offices	21.0%	Practitioners were provided with one biological indicator unit per sterilizer, with instructions for using them. In total, 62 autoclaves were tested once.

Table 3.1 summarizes the steam sterilization failure rates reported by such studies. In most studies, the practitioners were given biological indicator strips/ampoules and asked to include them in their autoclave cycles to test sterility, and report the results. This method relied on the practitioners' appropriate use of the indicators and reliable reporting of the results. The sterilization failure rates reported by these studies must be interpreted in this context. It is possible that reported failure rates were lower than the actual failure rates in these healthcare facilities.

3.1.1 Current evidence for autoclave effectiveness

Globally, the number of published studies measuring the effectiveness of autoclave practices using biological indicators is small; the reason for this is uncertain. The number of studies reported from developed countries is also small. This might be because strict regulatory requirements, use of sophisticated technologies and the availability of trained staff has created a degree of complacency among researchers, meaning that they do not see the necessity for such studies. However, medical device-associated infections have been reported from developed countries; therefore, monitoring and documenting the effectiveness of autoclave practices in these countries cannot be neglected. On the other hand, most developing countries are likely dependent on less sophisticated autoclaves and under-skilled operators, which might lead to sterilization failures. Clearly, evidence for the effectiveness of sterilization practices in these countries is crucial. Studies in India, Kenya and Mexico showed comparatively higher rates of sterilization failure i.e. 12.0%, 31.0%, and 21.0% respectively than in Canada, UK, Denmark, Hong Kong and Iran i.e. 2.3%, 1.5%, 4.5%, 7.0%, and 2.9% respectively (Burke *et al.*, 1998; Kelkar *et al.*, 2004; McErlane *et al.*, 1992; Miranzadeh *et al.*, 2013; Okemwa *et al.*, 2014; Patiño-Marín *et al.*, 2015; Scheutz & Reinholdt, 1988; Wai-Kwok & Chi-Ming, 2007). These studies were conducted during different periods of time, 95% confidence intervals were not reported in any of the studies, and hence, the results may not be directly comparable. In addition, as the number of bacterial spores contained in the biological indicator strips or vials is not known for most of the studies, extra caution needs to be taken to compare the findings of these studies. It is also important to note that the studies in India and Iran were conducted in eye care hospitals and general government hospitals respectively whereas rest of the studies were conducted in dental care facilities.

From the global literature there appears to be no declining trend in sterilization failures. A study published in 1998 reported a low sterilization failure rate (i.e.1.5%) in dental practices in the UK (Burke *et al.*, 1998). However, recent studies from Kenya and Mexico show sterilization failure rates in dental practice of 31.0% and 21.0% respectively (Okemwa *et al.*, 2014; Patiño-Marín *et al.*, 2015); it is noteworthy that the sample sizes for these studies were smaller compared to many other dental practice studies (Healy *et al.*, 2004; Miranzadeh *et al.*, 2013; Wai-Kwok & Chi-Ming, 2007). The majority of the studies showed sterilization failure rates of greater than 6%, indicating a need for improvement.

3.1.2 Autoclave effectiveness in general healthcare facilities

There is very little evidence about the effectiveness of autoclave practices in general healthcare facilities (including all levels of hospitals, e.g. primary, secondary and tertiary). Most of the published studies of sterilization effectiveness are concerned with the effectiveness of the use of autoclaves in dental practice. Coulter *et al.* (2001) conducted a study on autoclave performance in primary care practices in the UK and found a sterility failure rate of 2.0% using biological indicators. However, this failure rate was reported by the respondents of the self-administered postal surveys after performing the tests themselves. This could have introduced bias. Miranzadeh *et al.* (2013) conducted a study in Iran which included six general government hospitals in Iran and reported a failure rate of 2.9%.

3.1.3 Evidence about the effectiveness of autoclaving in Nepal

Information about the effectiveness of steam sterilization of medical devices in Nepal is scanty. There is no available documentation about the effectiveness of autoclaving in public hospitals in Nepal.

A multi-centre pilot study of nine hospitals in seven low- and middle-income countries, was conducted by O'Hara *et al.* (2015) to assess steam sterilization of surgical instruments in those countries. Two hospitals from Nepal participated in this study, but the characteristics of these hospitals were not specifically reported. Class 5 chemical indicators were used to assess the steam sterilization cycles. According to the study, 22.2% (20 out of 90) of the steam sterilization cycles gave unacceptable results with the chemical indicators. Review of the

records submitted by the hospitals showed that not a single sterilization cycle out of 90 cycles had completely acceptable parameters for temperature or pressure.

In 2013, an USAID-funded project in Nepal carried out validation of 21 small pressure-cooker type autoclaves for sterilizing healthcare waste produced in small HIV care facilities run by non-governmental organisations (NGOs). Altogether 67 autoclave cycles were tested and growth of *Bacillus stearothermophilus* spores was observed after 18 cycles i.e. 26.8% (USAID Saath-Saath Project, 2013). For the validation, autoclaves were operated and tested by trained autoclave operators following a standard validation protocol. The results obtained from such validation activities cannot be generalized as representing the effectiveness of routine autoclaving practices in the hospitals in Nepal because it is not clear that all autoclaving practices follow standard validations protocols. Tao (2012) documented that the vast majority of medical equipment in Nepal, including autoclaves, is imported from India. Most of those autoclaves used in the above HIV-care facilities were also imported from Indian manufacturers. Therefore, district hospitals and district-level hospitals in Nepal are likely to have autoclaves similar to those possessed by the HIV-care facilities.

The information discussed above provides some signals about the effectiveness of steam sterilization of medical devices in healthcare facilities in Nepal, but no scientific studies on the effectiveness of routine moist-heat sterilization practices in both public and private healthcare facilities in Nepal are available. There is a need for such studies to understand the effectiveness of moist-heat sterilization in these hospitals. Such studies will be crucial for improvement of medical device reprocessing across hospitals in Nepal.

3.2 Factors Determining the Effectiveness of Sterilization

Documented factors associated with sterilization failures are related to management, staff, sterilization processes, and/or equipment (e.g. autoclave). Absence of strict regulatory requirements, lack of appropriate instructions, lack of supervision, power failures, inadequate knowledge, inadequate sterilization temperature and time, improper packaging and loading, faulty equipment, and inadequate maintenance of equipment were considered as some of the factors associated with sterilization failures (Burke *et al.*, 1998; Messieha *et al.*, 1989; Wai-

Kwok & Chi-Ming, 2007). However, rigorous statistical analyses were not used to establish these associations.

3.3 Healthcare Workers' Knowledge and Attitudes

Adequate staff knowledge is fundamental to any healthcare practice. There are theories (for example, cognitive theories) which assume that lack of knowledge leads to undesirable practices in healthcare (Rowe *et al.*, 2005). Studies have shown that a significant proportion of health workers do not have adequate knowledge on some disinfection and sterilization issues (Allen *et al.*, 1997; Keah *et al.*, 1995; McNally *et al.*, 2001; Smyth *et al.*, 1999). These studies indicate that inadequate knowledge among healthcare staff about the reprocessing of medical devices exists in developed countries as well.

Allen *et al.* (1997) carried out a study to determine the level of knowledge among sterilizer operators working in general practice in the UK. Only 19.0% of the respondents understood the correct meaning of the term 'sterilization' but 90.0% of the respondents considered steam under pressure as an appropriate method for sterilization. In a study within university health services in the UK, only 52.0% and 32.0% of the respondents correctly identified definitions of sterilization and disinfection respectively, indicating the need for adequate education and training of staff within an academic environment as well (McNally *et al.*, 2001).

A study in Northern Ireland showed that only 25.0% and 34.0% of general practioners correctly identified definitions of sterilization and disinfection respectively. However, 95.0% of the respondents thought of "steam under pressure at 134°C for three minutes" as a recommended method for the sterilization of a solid object or instrument. In addition, 90% of the respondents felt that it was always necessary to clean items before sterilization (Smyth *et al.*, 1999).

Specific documentation about the extent of knowledge on the sterilization and reuse of medical devices among healthcare workers in Nepal could not be found. However, Paudyal, Simkhada and Bruce (2008) conducted a survey on knowledge, attitudes and practice in the area of infection control among Nepalese healthcare workers. The study found that profession, age, and having studied abroad significantly predicted markers of appropriate

knowledge, attitudes and practice in infection control. According to the study, "risk of infection associated with critically ill patients", "invasive devices", and "inappropriate use of antibiotics" were the specific areas where knowledge among healthcare workers was lacking. Healthcare workers have different academic qualifications and demographic characteristics; and their level of knowledge on a particular issue may vary accordingly.

Studies investigating the attitudes of healthcare workers towards reprocessing and reuse of medical devices are rare. However, some studies have investigated the attitudes of healthcare workers towards some elements of infection control in healthcare facilities. Sessa *et al.* (2011) assessed the attitudes of nurses towards the utility of guidelines for disinfection procedures using a rating scale ranging from 1 to 10 where a higher score indicated a more positive attitude. The author reported a mean score of 9.1 and a more positive attitude was found in female nurses (compared to male nurses, $p = 0.01$), in nurses with a shorter experience ($p = 0.03$) and in the nurses who felt that they needed additional information about disinfection (compared to those who didn't feel the need, $p < 0.05$). Stein, Makarawo and Ahmad (2003) compared the attitudes of doctors and nurses towards universal precaution practices, such as washing hands before and after patient contact and wearing gloves during blood collection, in three teaching hospitals in Birmingham, UK. A better attitude was consistently found among nurses in this study compared with doctors. Another study from a tertiary-care hospital in western India reported high percentages of healthcare workers showing positive attitudes towards sterilization guidelines or policies (84.3%), and training of healthcare workers about sterilization and disinfection (78.4%).

3.4 Staff Training

Usually training about disinfection and sterilization of medical devices is integrated in general training on infection control and hence, the training materials are also developed accordingly. In a survey in the UK, Coulter *et al.* (2001) found that 55.0% of the respondents were trained in infection control but only 26.0% of the respondents had received specific training on autoclaving. Similarly, in Nepal, the training curriculum on "infection prevention and healthcare waste management" developed by the National Health Training Center (NHTC) incorporates a section on sterilization and disinfection (NHTC - Ministry of Health and Population - Government of Nepal, 2015a). This training curriculum is not a part of

academic nursing or medical courses. This training is offered to healthcare workers who have already been working in the healthcare facilities. Paudyal *et al.* (2008) found that 27.0% of Nepalese healthcare workers were trained in infection control. However, whether an isolated training session on autoclaving or general training on infection prevention will be better for ensuring adequate sterilization of medical devices is unknown. Skills gained by healthcare workers during training may not always be implemented successfully in their work place (Grol & Grimshaw, 2003), so, it is important to understand how well skills gained from training are implemented in the workplace.

3.5 Compliance with Recommended Practices

There are national/international guidelines and standards related to the reprocessing and reuse of medical devices. Nepal does not have specific policies and guidelines for reprocessing of medical devices in healthcare facilities. The only guidance on disinfection and sterilization provided to healthcare facilities and staff is through a reference manual on "infection prevention and healthcare waste management" (NHTC - Ministry of Health and Population - Government of Nepal, 2015a). The extent of compliance of healthcare staff with the instructions provided by the reference manual is not well understood.

Many studies have reported non-compliance of healthcare workers with recommended reprocessing practices. Bonetti *et al.* (2009) undertook a survey of a random sample of 200 general dental practitioners in Scotland (response proportion 57%), and reported that 30% of general dental practitioners were unsure about the practice of following written policies while cleaning devices within the practice.

Monitoring each steam sterilization cycle with physical, chemical and/or biological indicators and recording the results, have been recommended by guidelines and standards. Variations in the frequency of use of chemical and biological indicators have been documented in different countries and places (Coulter *et al.*, 2001; Gurevich, Dubin & Cunha, 1996; Matsuda *et al.*, 2011). In a postal survey carried out by Gurevich *et al.* (1996), 11,000 dental practices from the east coast of the USA were requested to complete a questionnaire; 1391 (about 13%) of them returned the completed questionnaire and 1321 of them reported use of autoclave for sterilizing some medical devices. Of the practices using autoclaves, only 53.5% used

biological indicators at least weekly to monitor the effectiveness of autoclaves to sterilize dental instruments. More recently, Matsuda *et al.* (2011) distributed a self-administered survey questionnaire to 677 dental surgeons enrolled in specialization courses in the Municipality of Sao Paulo, Brazil and 614 (i.e. 90.7%) of them returned the completed questionnaire; 69.4% of the respondents were using autoclaves for sterilizing dental instruments and 33.8% of them were not monitoring the performance of autoclave cycles using biological and/or chemical indicators. Coulter *et al.* (2001) randomly sampled 700 medical practices from a list of 7500 medical practices in twelve Health Authorities in England and Wales and distributed a questionnaire; 53.1% (n = 372) of them completed the questionnaire. According to this study, chemical strips/tapes were used in each autoclave cycle by 15% of the respondents; 5% of the respondents used the strips once per day; 11% used once per week; 4% used once per month; and 65% never used this method of monitoring. On the other hand, none of the respondents used biological indicators. A recent study conducted among dental care offices in Mexico found that 20 out of 62 (i.e. 36%) of dental care offices were using biological indicators to monitor the effectiveness of moist heat sterilization (autoclaving) practices (Patiño-Marín *et al.*, 2015). These findings show inconsistencies in the use of biological and chemical indicators for routine monitoring of autoclaves' performance across the globe. The frequency of use (if any) of such indicators in healthcare facilities of Nepal has not been documented.

A gap analysis of infection control practices in low- and middle-income countries was carried out by Weinshel *et al.* (2015). An academic hospital with 700-bed capacity from Nepal participated in the gap analysis. The Infection Control Assessment Tool (ICAT), developed by the US Agency for International Development, was used for the gap analysis. The analysis showed that the hospital from Nepal was following 60% of the recommended practices in the area of policies and procedures related to sterilization and infection control. The hospital was found to be following 45% of the recommended practices in the areas of sterilization and disinfection of instruments and equipment. The study also showed that 80% of the recommended practices in the area of steam sterilization (autoclaving) were followed by the hospital.

3.6 Sterilization Equipment

Autoclaves used for sterilization of medical devices can be a basic pressure-cooker type, gravity displacement type or pre-vacuum type. Pre-vacuum autoclaves are superior to gravity displacement autoclaves in killing microorganisms as complete displacement of air by steam in the autoclave chamber can occur (McDonnell & Sheard, 2012). Periodic validation, and routine maintenance of autoclaves have been recommended in various guidelines and standards. Validation includes the installation qualification, performance qualification and operational qualification of autoclaves used for sterilization of medical devices (ISO, 2006; Rutala *et al.*, 2008; U.S. Food and Drug Administration, 2015; WHO, 2007a). Shintani (2012, p. 57) described the importance of validation as "autoclaves and support systems need to be designed, installed, and qualified in a manner that ensures their continued reliability". A validation survey of 197 sterilizers in the Netherlands found that only 40% of the validated autoclaves met the required norms and standards (Van Doornmalen & Dankert, 2005). In the absence of mandatory requirements for periodic validation of medical equipment in Nepal, the performance of the autoclaves in Nepal could also be problematic.

3.7 HIV and Medical Device Reprocessing

With the emergence of blood-borne pathogens such as HIV, HBV and HCV, there has been apprehension among healthcare workers about the transmission of such viruses from infected patients to healthcare workers and other patients. In a survey on attitudes toward HIV-infected individuals among dentists in Mexico City, 35% of the respondents perceived the risk of HIV infection as "considerable" to "very strong" (Maupomé *et al.*, 2000). A similar survey among private dental practitioners in Fars province of Iran showed that 90.6% of the respondents were anxious about the perceived increase in risk of HIV in their practice (Askarian, Mirzaei & McLaws, 2006). Such apprehension can lead to discriminatory attitudes and practices among healthcare workers towards patients infected with the viruses (Mahendra *et al.*, 2007; Reis *et al.*, 2005).

Deviation from routine infection control practices, including routine reprocessing procedures for medical devices may occur due to the fear of transmission of the viruses from contaminated medical devices. A study in Massachusetts showed that healthcare workers

from seven out of eight hospitals stated that they would deviate from routine reprocessing procedures for flexible fibreoptic endoscopes (FFEs) when devices had been used in patients with AIDS or other diagnoses such as hepatitis or tuberculosis, even though altered procedures were not specified in the formal written or verbal protocols. The study also found that specific devices were reserved for the exclusive use of patients with AIDS in one reprocessing area. This has been described as "an obvious violation of the principles of universal precautions" by the authors (Reynolds *et al.*, 1992). Similar findings were obtained in another study by Rutala *et al.* (1991).

According to the Joint United Nations Programme on HIV/AIDS (2016), it is estimated that currently 32,000 (95% CI 28, 000 – 38,000) people in Nepal are living with HIV, with an HIV prevalence of 0.2 % (95% CI 0.1% - 0.2%) in adults aged 15-49 years. The attitudes of healthcare workers towards reprocessing of medical devices used for HIV-positive patients have not been well explained. However, denial of healthcare, including dental care by healthcare facilities/workers, to people living with HIV in Nepal has been documented (Family Planning Association of Nepal, 2011). It would be important to understand how the HIV status of patients influences the reprocessing and reuse of medical devices in hospitals in Nepal.

3.8 Significance of Evidence

The literature discussed above clearly indicates that further robust (e.g. using reliable indicators of sterilization) studies are necessary to draw firm conclusions about autoclave effectiveness in developing countries including Nepal. However, from the data available it can be postulated that there could be a high proportion of sterilization failure in health facilities in the developing world, but many of the studies relate to dental practices, which might not extrapolate to higher-level health care facilities. The reasons for sterilization failures are unclear from the published studies. There is a need to explore reasons for such failures in order to formulate interventions to improve reprocessing and reuse of medical devices in Nepal.

CHAPTER 4. METHODS

This chapter will describe the study design, study tools, sample size calculations, sample selection, and data collection procedures used in this study. It will also provide information about data management, and ethical considerations pertaining to the study.

4.1 Study Design

This was a quantitative descriptive cross-sectional study. According to Polit and Beck (2010, p. 565), quantitative research is "the investigation of phenomena that lend themselves to precise measurement and quantification, often involving a rigorous and controlled design". Descriptive studies are observational studies and are considered to "describe" a health phenomenon in terms of its distribution across person, place and time. These studies are appropriate for health problems about which little is known and are also useful for estimating prevalence of a disease or exposure. In addition, descriptive studies are helpful for tracking changes over time (Bailey & Handu, 2013).

This study fits within the category of 'health services research'. Bowling and Ebrahim (2005) describe health services research as studies seeking knowledge and evidence that lead to improvements in the delivery of health care. This study had a purpose of providing baseline information and recommendations for improving sterilization of reusable medical devices in primary and secondary care hospitals in Nepal, with an ultimate goal of contributing to the prevention of HAIs (Section 1.6).

Different objectives of this study (Section 1.6) necessitated multiple aspects within the study design. These aspects of the study are discussed below with respect to each research objective.

Understanding the characteristics of the primary and secondary care hospitals (Objective 1, Section 1.6): Information related to the characteristics of the hospitals in terms of reprocessing and reuse of medical devices was collected using a 'Hospital Summary Information' sheet. The sheet comprised two sections- general information and information related to medical device reprocessing. The information to be recorded in the sheet was

obtained either by observation or by interviewing key people. Development and use of the summary information sheet are further discussed in sections 4.2.4 and 4.6.4. The process of collecting basic information about a hospital can be considered as a form of evaluation as this helps in defining, exploring and documenting the processes and mechanisms underpinning the medical device reprocessing system in the hospital (Belling, 2013).

Investigating knowledge and attitude of healthcare workers (Objective 2, Section 1.6): To investigate the knowledge and attitudes of healthcare workers about sterilization and reuse of medical devices, a survey was undertaken. Surveys are useful for describing a population and identifying possible associations between variables, through collection of quantified data. Survey results may point towards causal relationships or predictive patterns of influence (McLaren, 2013), but it is important to acknowledge that descriptive studies cannot determine causation. According to Whittaker (2012), surveys are suitable for identifying beliefs, attitudes, behaviours and other characteristics of large populations. Surveys can use various means of data collection including questionnaires, indicators and biological and psychological measures. In this study, a questionnaire was used for the objective of investigating the knowledge and attitudes of healthcare workers towards sterilization and reuse of medical devices. Development of the survey questionnaire and its administration to healthcare workers are described in sections 4.2.2 and 4.6.3.

Exploring routine practices for sterilization of medical devices (Objective 3, Section 1.6): To achieve the objective of exploring routine practices for sterilization and reuse of medical devices in the primary and secondary care public hospitals in Nepal, audits were carried out. Generally, audits are carried out in healthcare to measure performances against pre-specified criteria and standards. Such criteria or standards are developed based on guidelines, international norms of practice or performance targets (Naughton, 2013). An audit tool comprising standards for moist-heat sterilization practices in the primary and secondary care public hospitals was developed based on a number of studies, national/international guidelines and standards. Development of the audit tool and its administration procedures are discussed in detail in sections 4.2.3 and 4.6.2. Conventionally, audits are carried out to study parts of the structure, process or outcome of healthcare by the individuals who themselves are involved in the relevant healthcare activities (Sheldon, 1982). However, currently, audits are usually conducted by individuals or teams external to the healthcare environment (Johnston *et al.*, 2000). This audit exploring routine practices for moist-heat sterilization was carried out

by the researcher who was external to the hospital environments. Sometimes, a distinction is made between research and audit – research being considered as discovering the right thing to do and audit being considered as ensuring that the thing is done properly (Smith, 1992). However, in reality, both share similar design principles, methodologies and data-analysis strategies, and both are aimed at generating reproducible, valid and reliable data (Naughton, 2013). Audit has also been sometimes considered as a type of evaluation research applied for monitoring and assessing the quality of healthcare activities (Clarke & Dawson, 1999).

Measurement of the effectiveness of steam sterilization practices (Objective 4, Section 1.6): The effectiveness of the steam sterilization practices in the primary and secondary care public hospitals was measured using some standard scientific tools (i.e. indicators). These tools and procedures used for measuring the effectiveness are described in detail in sections 4.2.1 and 4.6.1. Such a measurement of the effectiveness of a process is considered as evaluation research (Clarke & Dawson, 1999). Effectiveness of an activity or a process is measured by evaluating whether goals and objectives have been achieved (Belling, 2013). Effectiveness of a steam sterilization cycle can be measured by evaluating its ability to achieve the objective of killing a number of microorganisms which are most resistant to moist-heat; spores are the most resistant forms of bacteria (Section 2.4). Data are collected systematically and rigorously in evaluation research (Bowling, 2009). A scientific approach, which is commonly used in quantitative research (Belling, 2013), was used to measure the effectiveness of steam sterilization cycles.

Considering potential causes of steam sterilization failures (Objective 5, Section 1.6): Data from the survey, the audit and the evaluation were analysed to identify possible factors associated with steam sterilization failures (sections 6.6, 6.7.5, 9.4).

Determining the quality of water (Objective 6, Section 1.6): The quality of water used for reprocessing of medical devices in the hospitals was evaluated in terms of its pH and total hardness (Section 2.5.1). Tools and procedures used for measuring the pH and the total hardness of water are described in detail in sections 4.2.6, 4.2.7, and 4.6.5.

Making recommendations (Objective 7, Section 1.6): Based on the findings of the different aspects of the study discussed above, recommendations for improving medical devices

reprocessing in the hospitals and for reducing the potential risk of HAIs due to the reuse of medical devices were made (Section 9.11.2).

4.2 Study Tools

4.2.1 Indicators

One of the key objectives of the study was to investigate the effectiveness of steam sterilization cycles (autoclaving practices) in sterilizing medical devices in primary and secondary care hospitals in Nepal. Effectiveness reflects the probability of obtaining sterile medical devices in everyday practice (Brook & Lohr, 1985). It was measured using biological and chemical (class 1 and class 5) indicators, as described below.

Biological indicators: Self-contained biological indicators containing 1.3 x 10^6 spores of *Geobacillus stearothermophilus* were used to determine the effectiveness of steam sterilization cycles. Indicators were placed in sites inside autoclave loads where it was most difficult for the steam to penetrate according to the manufacturer's instructions. Once a sterilization cycle was completed, the indicators were incubated at an appropriate temperature for the recommended period of time. If the indicators showed the growth of the organism (indicated by a change in colour), the sterilization was considered as ineffective. However, if the indicators showed no growth, the cycle was considered effective. **ProSpore 2 Self-Contained Biological Indicators** manufactured by Mesa Labs Inc., Omaha, USA were used in this study (Mesa Labs Inc., 2015c). This product was selected based on its commercial availability in Nepal, its compliance with the requirements of ISO 11138-1 and ISO 11138-3 (Appendix 8), commercial availability of a portable incubator to incubate indicator tubes and researcher's prior experience of using the product.

Chemical Indicators: Chemical indicators are available in the form of reagent strips. When exposed to particular physical change (e.g. temperature) or concentrations of a test chemical (i.e. specified "stated values"), these indicators reach their end point indicated by either a change in a colour or a migration of a coloured band into the "accept" area. Stated value (SV) is defined as "value or values of a critical variable at which the indicator is designed to reach its endpoint as defined by the manufacturer" (Association for the Advancement of Medical

Instrumentation, 2005, p. 2). Chemical indicators have been categorised into different classes ranging from class 1 to class 6. Each class of indicators has different interpretations when using them with steam sterilization cycles. Class 1 indicators are used to determine whether a package is exposed to a sterilization process while class 5 indicators are used as an internal indicator for pack control monitoring. Class 5 chemical indicators are also known as "integrating integrators" and simulate the response to a biological indicator (McDonnell & Sheard, 2012). They are designed to react to all critical variables including time, temperature and water. **ProChem Process Indicator Tape** (class 1 chemical indicator) and **ProChem SSW Steam Sterilization Integrator** (class 5 chemical indicator) manufactured by Mesa Labs Inc., Omaha, USA were used in this study (Mesa Labs Inc., 2015a; Mesa Labs Inc., 2015b). **ProChem SSW Steam Sterilization Integrator** was also selected based on its commercial availability in Nepal, its compliance with the requirements of ISO 11140-1 (Appendix 9) and researcher's prior experience of using this product. These indicators were used, and the results were interpreted, according to the manufacturer's instructions. Use of these indicators for assessing effectiveness of steam sterilization cycles is further discussed in Section 4.6.1.

Pressure gauges: Pressure gauges incorporated in the autoclaves by the manufacturers were used to observe and record the pressures inside the autoclave chambers during the sterilization process.

4.2.2 Knowledge and attitude questionnaire

A questionnaire consisting of elements assessing the knowledge and attitudes of healthcare workers towards sterilization of medical devices was developed and used (a copy of the questionnaire is included as Appendix 1). The questionnaire had three different sections. The first section (Section A) of the questionnaire was designed to collect demographic information about the healthcare worker participating in the survey. The demographic information included information related to gender, age, education, experience in healthcare, and employment status. The second section (Section B) of the questionnaire included items related to knowledge on sterilization and reuse of medical devices. The section contained categorical response items (for example, yes/no questions), open ended questions, and rating scale items. The rating scales had a minimum value of one and a maximum value of seven.

Seven point scales have been found to provide the best compromise between too few scale points and too many scale points (Groves, 2009). The third section (Section C) of the questionnaire contained items related to the attitudes of healthcare workers towards sterilization and reuse of medical devices. All of the items in this section were rating scale items. Some of the rating scale items in both knowledge and attitude sections were deliberately worded negatively to minimize the tendency of participants to agree with all statements regardless of the content. Such tendency of agreeing with all the sentences is also known as "acquiescent response bias" (Lavrakas, 2008).

Development of the questionnaire: A literature search was conducted to identify studies focussing on knowledge and attitudes of healthcare workers towards sterilization and reuse of medical devices in different countries. Keywords used for searching studies included, but were not limited to 'sterilization', 'disinfection', 'medical devices', 'knowledge', 'attitude', 'survey', 'reprocessing', 'autoclave', 'infection control' and 'decontamination'. Studies published in English were searched in online databases including Google Scholar, Medline and CINAHL. References of the studies obtained from the search were also checked and additional articles were downloaded. Ten studies were identified and thoroughly reviewed (Allen *et al.*, 1997; Coulter *et al.*, 2001; McNally *et al.*, 2001; Morgan *et al.*, 1990; Nobile *et al.*, 2002; Sexton *et al.*, 2006; Spry, 2008; Walker, Paulson & Jenkins, 1997; Williams *et al.*, 1994; Zimakoff *et al.*, 1992). Based on those studies and some national/international guidelines and standards on sterilization of medical devices (2009; ISO, 2006; ISO, 2009; (NHTC - Ministry of Health and Population - Government of Nepal, 2015b; Rutala *et al.*, 2008; Standards Australia & Standards New Zealand, 2014), a draft questionnaire was developed. Two items related to the attitudes of healthcare workers towards HIV and reprocessing of medical devices were based on three previous studies (Askarian *et al.*, 2006; Kermode *et al.*, 2005; Maupomé *et al.*, 2000). One attitude item in the questionnaire was adapted from an article in a publication for purchasers of healthcare equipment (Hubbard, 2010).

The first draft of the questionnaire was shared with supervisors, a biostatistician and experts from both Nepal and New Zealand for their comments and feedback. They were requested to check whether the items in the questionnaire represented knowledge and attitudes in the area of medical device sterilization and reuse, whether the items are appropriate for the study population i.e. healthcare workers, and whether the items in the questionnaire are clear.

Comments and feedback received were further discussed with the supervisors. The questionnaire was revised incorporating relevant feedback and comments. The items in the revised questionnaire were also translated into Nepali language by the researcher. The translated items were added into the main questionnaire, so the questionnaire included items in both English and Nepali languages. The purpose of the translation was to facilitate response by the healthcare workers who were less proficient in English language. The revised questionnaire was submitted to the Human Ethics Committee of the University of Canterbury for review and approval. Field-testing of the questionnaire was conducted in one of the district hospitals in Nepal. Eighteen knowledge and attitude questionnaires were completed by healthcare workers of different levels. The respondents (i.e. healthcare workers) were asked to provide feedback on the questionnaire including clarity of the items, time required to complete the questionnaire and appropriateness of the items. Feasibility of the questionnaire administration technique was also examined during the field testing. In light of the feedback obtained from the respondents and the experiences gained in the field, further modifications were made to the questionnaire. One of the major findings from the field testing was that autoclave operators (office assistants) were not able to complete the questionnaire on their own because of their poor literacy, so an alternative to self-administration of the questionnaire was developed. The revised questionnaire was then submitted to the Nepal Health Research Council (NHRC) for a final review and approval. This whole process of questionnaire development helped ensure the validity of the questionnaire (Marshall, 2005). Figure 4.1 outlines the process used for the development of the questionnaire.

4.2.3 Audit tool: moist heat sterilization

An audit was developed and used to assess and explore reprocessing of medical devices using moist-heat sterilization (autoclaving) in the hospitals (a copy of the audit tool is included as Appendix 2). The tool comprised different sections related to medical device reprocessing with moist-heat sterilization. The sections in the tool were general, transport, cleaning and disinfection, inspection, packaging, sterilization (autoclaving), and transport, storage and use. Each section of the tool included basic elements required for moist-heat reprocessing of medical devices in healthcare facilities.

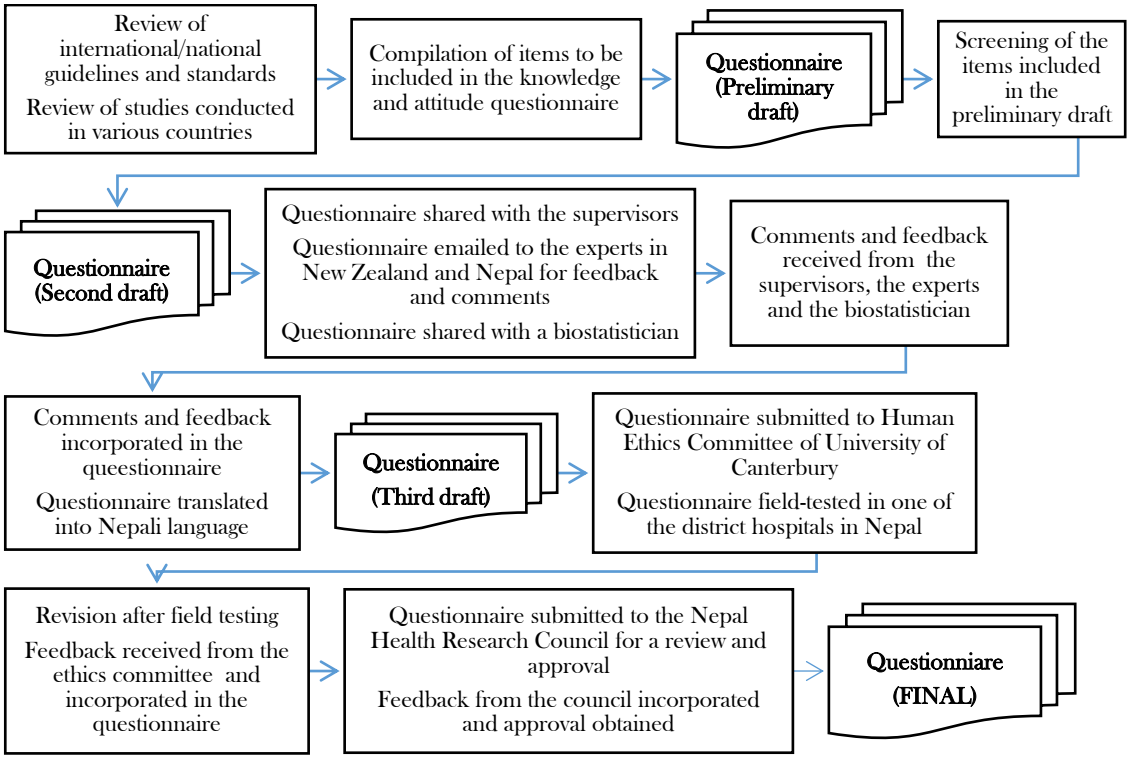

Figure 4.1: An outline of the questionnaire development process

Development of the audit tool: For developing the audit tool, as for developing the knowledge and attitude questionnaire, a literature search was carried out to identify studies/articles in the area of medical device reprocessing and reuse. Key words including, but not limited to, 'decontamination', 'sterilization', 'reprocessing', 'disinfection', 'reuse', 'medical device', 'hospital', 'instruments', 'infection control', 'audit' and 'standards' were used to obtain relevant articles from databases including Google Scholar, Medline and CINAHL. References of the articles obtained the search were also checked and relevant articles were downloaded. Altogether 9 articles were identified (Bagg *et al.*, 2007; Bonetti *et al.*, 2009; Cooper, Tait & Bingham, 2003; Danchaivijitr, 2005; Finn & Crook, 1998; Matsuda *et al.*, 2011; McNally *et al.*, 2001; Smith *et al.*, 2007a; Smith *et al.*, 2007b). In addition, 13 national/international guidance documents, worksheets and standards on infection control and reprocessing of medical devices were also identified (Acosta-Gnass & Stempliuk, 2009; CDC, 2014; Centers for Medicare and Medicaid Services, 2013; Centers for Medicare and Medicaid Services, 2015; ISO, 2006; ISO, 2009; ISO, 2013; NHTC - Ministry of Health and Population - Government of Nepal, 2015a; NHTC - Ministry of Health and Population - Government of Nepal, 2015b; Provincial Infectious Diseases Advisory Committee - Public Health Ontario, 2013; Rutala *et al.*, 2008; Scottish Dental Clinical Effectiveness Programme, 2014; Standards Australia & Standards New Zealand, 2006). These studies and documents

were thoroughly reviewed and a draft tool was developed. The first draft of the audit tool was shared with supervisors, a biostatistician and experts from both Nepal and New Zealand for their comments and feedback. Comments and feedback received were further discussed with the supervisors. The tool was revised by incorporating relevant feedback and comments. Field-testing of the tool was conducted in one of the district hospitals in Nepal to examine the appropriateness and clarity of the tool. The tool was finalized by making required modifications after the field testing.

4.2.4 Hospital summary information sheet

A Hospital Summary Information sheet was developed and used to collect general information about the hospitals included in the study, including hospital type, number of beds, staffing, and availability of clinical services. The sheet was also used for collecting general information about reprocessing of medical devices in the hospitals. Such information included decontamination activities performed in the hospitals, availability of relevant policies and guidelines, number of autoclaves in operation and information specific to the autoclaves. The information sheet was developed using the same process as the audit tool (a copy of the Hospital Summary Information Sheet is provided as Appendix 3).

4.2.5 Test results form

A form was developed and used to record results of chemical and biological indicators used for testing the autoclave cycles. The same form was also used for recording pressures within an autoclave chamber during a sterilization process (a copy of the form is included as Appendix 4).

4.2.6 Water hardness meter

An HI 96735C Hardness meter (Hanna Instruments Inc., Woonsocket) was used for measuring the hardness of the water used for reprocessing of medical devices in the hospitals. The HI 96735C is an auto diagnostic portable microprocessor meter with an advanced optical system based on a Light Emitting Diode (LED) and a narrow-band interference filter that allows accurate and repeatable readings. The meter measures the hardness content as Mg^{2+}

and Ca^{2+} in water samples in the 0 to 750 mg/L (ppm) $CaCO_3$ range (Hanna Instruments Inc., 2016).

4.2.7 Water pH meter

A FG2/EL2 Portable pH Meter (Mettler Toledo, Schwerzenbach) was used to measure the pH of water used for reprocessing of medical devices in the hospitals. The meter had a capacity to measure water pH ranging from 0.00 to 14.00, a precision of 0.01 pH units and an accuracy of ± 0.01 pH units.

4.3 Sample Design

Zonal, district and district-level hospitals were included in the study (Section 1.5). There were 10 zonal hospitals, 62 district hospitals and 16 district-level hospitals in Nepal (Department of Health Services - Ministry of Health and Population - Government of Nepal, 2015). Given the three types of hospitals with different attributes, a stratified design with three strata was used. Hospitals were sampled from within each stratum and simple proportional allocation of hospitals within each stratum was used. Each hospital represented a cluster of observations (the repeated sampling of the autoclave cycle) and the key outcome measure for each observation was the binary variable 'accepted (effective)' or 'rejected (non-effective)' with respect to sterilization effectiveness.

Cluster-Sample Design: It was impractical to take a random sample of steam sterilization (autoclave) cycles across all zonal, district and district-level hospitals in Nepal. In this situation, a cluster-sample design was the only practical solution (Bennett *et al.*, 1991). The sampling strategy was developed in consultation with a biostatistician.

The sample design was driven by the accuracy required of the key outcome measure. Here, the key outcome measure was a proportion of steam sterilization practices giving desired results, as assessed using biological or chemical indicators. The process firstly considered - what was a 'reasonable' estimate of required observations, assuming random sampling of units and making an assumption that each hospital could provide a number of repeated

measures? This sample size was then adapted to adjust for the fact that we would be sampling clusters of measurements.

In a cluster sample, units that belong to the same cluster are more similar to each other than to units in another cluster, so the number of sample units, *n*, does not reflect the number of distinct units in a simple random sample of the same size. The Design Effect (DEFF) gives the factor by which the number of cases of a simple random sample can be decreased and still have the same precision as the realized cluster sample (Bennett *et al.*, 1991).

The key drivers of the sample size were the margin of error required (the confidence interval is calculated from estimate +/- margin of error) and the assumption about the impact of the clustering, measured by 'roh' (the intra-class correlation coefficient), which drives the calculation of the DEFF. Rho lies between 0 and 1 and its magnitude depends on the characteristics of the specific variable and the population under study. Ideally an estimate of rho would come from a previous similar survey, but was not available for this study. Very few surveys quote either rho or DEFFs, so, it was difficult to determine a 'reasonable' value.

A value of rho = 0.2 resulted in estimated DEFFs between 3.2 and 3.8 for the stratum-level effects which seemed reasonable. Typically, large national household level complex surveys have DEFFs in the order of 2. For example, the 2015-16 New Zealand Health Survey had DEFFs ranging from 1.3 to 1.9 for key variables (Ministry of Health - New Zealand Government, 2016). Our study was expected to have larger design effects because it is a much smaller survey.

4.4 Sample Size

Autoclave cycles (for testing and audit): Based on the sample design described above, the numbers of hospitals to be randomly sampled from zonal hospitals, district hospitals and district-level hospitals were determined to be 2, 9 and 2 respectively. The number of moist-heat sterilization practices (autoclave cycles) to be observed and tested in each hospital were 12, 15 and 15 for zonal hospitals, district hospitals and district-level hospitals respectively. Thus, the total number of autoclave cycles to be observed was 189 (Table 4.1). For the purpose of sample size estimation, an assumption of sterilization rejection (failure) rates of

15%, 15% and 10% was made for district-level, district and zonal hospitals respectively. This assumption was based on the failure rate (obtained with class 5 chemical indicator) reported by O'Hara *et al.* (2015) in two hospitals in Nepal and on the failure rates reported previously in different countries (Table 3.1). It was also assumed that the sterilization failure would be comparatively smaller in secondary care hospitals than in primary care hospitals. Considering the intra-class correlation coefficient 0.2 for each category of hospitals and the confidence level 95%, the sample size of 189 was estimated for the stratified clustered design with a margin of error of 0.09. The design effects of 3.8, 3.8 and 3.2 were obtained for the district hospitals, the district-level hospitals and the zonal hospitals respectively.

Table 4.1: Sample sizes for testing of autoclave cycles in different hospital categories

Hospital category	**Number of hospitals**	**Sampled hospitals**	**Autoclave cycles tested in each hospital**	**Autoclave cycles tested in each hospital category**
Zonal hospital	10	2	12	24
District hospital	62	9	15	135
District-level hospital	16	2	15	30
Total number of autoclave cycles tested				**189**

The number of autoclave cycles to be audited was equal to the number of cycles to be tested with the chemical and biological indicators i.e. 15 autoclave cycles were to be audited in each of sampled district and district-level hospitals. Similarly, 12 autoclave cycles were to be audited in each sampled zonal hospital. Therefore, a total of 189 cycles was to be audited.

Water samples for pH and Hardness: The sample size for measuring pH and hardness of water was equal to the number of autoclave cycles to be tested and audited, i.e. 189 water samples were tested for pH and hardness.

Survey Participants: Items in the survey questionnaire had rating scales with a minimum value of one and a maximum value of seven. It was expected that the distribution would be skewed and so its shape was approximated by a right-angled triangle. Considering a margin of error of 0.3 and 95% level of confidence, the sample size was determined to be 85.

4.5 Sample Selection

Hospitals: Sampling within each hospital type was random and was carried out within Excel. Each hospital was assigned a random number to four decimal places, between 0 and 1.Within each hospital type (and within each state for District hospitals), the hospitals were sorted in ascending order of random number. For zonal hospitals, the first 2 hospitals in the randomly ordered list were selected into the sample. Similarly, for district-level hospitals, the first 2 hospitals in the list were selected. For district hospitals, it was desired to have the sample spread across the seven states, so a systematic sampling method was chosen. A list of all district hospitals was made in order of state, with the hospitals randomly ordered within each state. Nine hospitals had to be selected from the list of 61 hospitals. For this, one hospital was randomly chosen first within the range 1 to 61 and then every 7^{th} (i.e. $61/9^{th}$) hospital was selected. The hospital where field-testing was carried out before was omitted from the whole process of sampling. Therefore, only 61 district hospitals were included in the sampling process.

Autoclave cycles: A total of 15 consecutive autoclave cycles was tested and audited in each of the selected district hospitals and district-level hospitals. Similarly, 12 consecutive autoclave cycles were tested and audited in each of the selected zonal hospitals. If more than one autoclaves were being used in a hospital, the total number of consecutive autoclave cycles tested in the hospital included testing of all autoclaves in use.

Water samples: Water samples corresponding to each of the autoclave cycles were collected and tested for hardness and pH.

Survey Participants: Field testing of the questionnaire indicated that it was practically impossible to make the survey sample in a small hospital a simple random sample. It was required to ensure that staff from each category including doctors, nurses, paramedics (health assistants and auxiliary health workers) and autoclave operators from each hospital received the survey questionnaire. The number of healthcare workers belonging to some categories such as doctors was very small making the simple random sampling practically impossible within a hospital. The questionnaires were distributed to as many healthcare workers as

possible. Careful consideration was taken to avoid biased distribution of the survey questionnaire among healthcare staff.

4.6 Data Collection Procedure

4.6.1 Measurement of effectiveness of autoclave cycles

The researcher carried out the measurement of the effectiveness of the autoclave cycles. The autoclaving processes under measurement were carried out by the usual autoclave operator as a part of normal routine in a hospital. All of the tested autoclave cycles in the hospital were not necessarily run by the same operator as there were more than one operators in some hospitals. The operators were informed about the testing process ahead of time. A ProSpore 2 Self-Contained Biological Indicator (Mesa Labs, Inc.; Catalog Number PS2-3-6-50) and a ProChem SSW Steam Sterilization Integrator (Mesa Labs, Inc.; Catalog Number CI-SSW), a class 5 chemical indicator, were labelled with the same observation code. Both the indicators were then packaged together by the autoclave operator in the same way as the actual medical devices were packaged and prepared for a particular autoclaving cycle. The same wrapping material was used for wrapping the indicators as that used for medical devices. The purpose of wrapping the indicators was to create the same barriers to the steam for both the indicators and the medical devices. A class 1 autoclave tape (Mesa Labs, Inc.; Catalog Number: CI-STP) was also affixed to the package of the indicator. The package with the indicators was then placed inside the autoclave load along with the packages of medical devices to be sterilized. If medical devices (wrapped or unwrapped) were kept inside a reusable steel container for sterilization, the indicators (wrapped or unwrapped) would also be kept inside the same container. The medical devices along with the indicators were autoclaved according to in-house procedures.

After the completion of the autoclave cycle, the indicator package was retrieved from the autoclave chamber. The autoclave tape was checked to see if there had been a change in colour. The result of the autoclave tape was recorded as ‘Colour changed’ or ‘Colour not changed’.

The package of the indicators was opened and the ProChem SSW Steam Sterilization Integrator was checked to see whether the dark bar had entered the accept window. The result of the indicator was recorded as 'Accepted' or 'Rejected'.

The Biological Indicator was taken out of the package, sealed, allowed to cool and then crushed. Then, the tube was incubated at 57°C for 24 h along with an additional control tube (unexposed to sterilization cycle) in a portable Incubator (Mesa Labs, Inc.; Model 1450). Following this, the tubes were examined to observe any change in the colour of the tube. If the tube exposed to sterilization exhibited a colour change to or toward yellow (positive test result), the sterilization cycle would be considered failed or ineffective. If the tube did not change colour (negative test result), the cycles would be considered successful or effective. The result of the indicator was then recorded as 'Positive' or 'Negative'. For the test to be valid, the control tube should have shown a change in colour to or towards yellow.

The detailed manufacturer's instructions for each of the indicators are provided as appendices 5, 6 and 7.

In addition to the testing of the autoclave cycles using biological and chemical indicators, the pressure gauge of the autoclave chamber was read every minute, starting from the beginning to the end of the autoclave cycle, and the pressures observed were recorded by the researcher. The same process was used for all 189 autoclaving processes.

4.6.2 Audit of medical device reprocessing cycles

All core processes of a medical device reprocessing (with steam sterilization) cycle were observed by the researcher and an audit tool (described in Section 4.2.3) was completed. Observed core processes included transportation, cleaning, inspection, packaging, autoclaving, and transportation and use. The same audit process was completed for all 189 medical device reprocessing cycles.

4.6.3 Knowledge and attitude survey

A survey questionnaire (Appendix 1), an information sheet (Appendix 21) and a consent form (Appendix 23) were provided to the healthcare workers. The healthcare workers were asked to read the information sheet and the consent form carefully, and to sign and return the consent form after agreement to participate in the survey. The participants were also asked to return the survey questionnaires to the researcher in person immediately after completion. The participants were given an opportunity to ask questions about the research. To minimize the likely collusion between the participants while completing the questionnaire, the questionnaires were distributed to the participants at different times on different dates.

There were some healthcare workers (e.g. office assistants) who had poor or no literacy and were not able to complete the questionnaire by themselves. For those participants, the researcher read both the information sheet and the consent form in front of each worker and asked him/her to sign on the consent form if s/he agreed to participate in the survey. Then, interviews were conducted by the researcher and a questionnaire was completed for each participant.

No payment was made to the staff who participated in the survey.

4.6.4 Collection of hospital summary information

One ‘Hospital Summary Information’ sheet was completed for each hospital. Information required to complete the sheet was obtained either from the staff working in the relevant sections in the hospital or by observation. Information such as number of beds in the hospital, number of staff, and available clinical services were obtained from hospital administration. Information related to reprocessing of medical devices such as infrastructure allocated for reprocessing, decontamination activities performed in the hospital and number of autoclaves in operation was obtained by observation. Information specific to each autoclave such as type, acquisition, installation, validation, availability of spare parts, heating systems, and availability of relevant documents was obtained either by observation or from the autoclave operator and the store staff. Information about budgeting was obtained from the staff working in the accounting section of the hospital.

4.6.5 Measurement of water pH and hardness

Water used for cleaning medical devices in each of the reprocessing cycles was sampled using a water sampling bottle, and tested for total hardness and pH. If the same water was used for two or more reprocessing cycles, the water was sampled only once and tested for hardness and pH using the hardness meter and the pH meter. The pH and the total hardness of the water were recorded after each testing. The detailed manufacturer's instructions for testing water for hardness and pH are provided in Appendix 10 and Appendix 11. The instruments used for testing water were calibrated once in a day during the testing period according to the manufacturer's instructions.

4.7 Data Management and Analysis

A unique number was assigned to each hospital and recorded on each tool used in the study. The sole purpose for assigning a unique hospital number to the forms was to allow analysis of different variables within and between the hospitals. Assigning a hospital number to the forms did not identify people who completed the knowledge and attitude questionnaire, or individuals involved in the sterilization processes.

Information from the completed questionnaires, audit tools and results forms was entered in a database (Excel spreadsheet) every day. The database was kept securely in a password protected folder in a personal laptop computer. Backup of the data was also maintained in a separate hard drive.

After the completion of field work, data in the spreadsheets was imported to the IBM SPSS Statistics 24 software. Imported data sets were checked for any errors and discrepancies. Identified errors and discrepancies were then corrected by referring to the completed questionnaires.

Descriptive analyses of chemical and biological test results, information obtained from audits, demographic information of survey participants, and knowledge and attitude responses were performed. The analysis included but was not limited to calculation of

proportions, assessing associations between variables, and some regression analyses. Results were compared across the three hospital types.

The statistical analysis was carried out in regular consultation with the biostatistician who had been consulted during the study design phase. In particular, the analysis needed to account for the complex survey design.

4.8 Ethical Considerations

An ethical clearance was obtained from the Human Ethics Committee of the University of Canterbury. In addition, an approval was obtained from the NHRC. Approval letters provided by these institutions are included as appendices 12, 13, 14 and 15. Furthermore, a letter was sent by the Curative Service Division, Ministry of Health, Nepal to the participating hospitals requesting them to provide the required support to the study. The letter by the Curative Service Division has not been included in this thesis as the letter identifies the hospitals selected for this study.

Written consent was obtained from the medical superintendent or official in-charge of each of the thirteen selected hospitals before initiating research activities in the hospitals. Written consents were also obtained from all healthcare workers participating in the knowledge and attitude survey. Written information about the study was provided to all the medical superintendents or the officials in-charge and the participants of the survey before receiving the written consents.

Completed survey questionnaires were kept confidential. Personal information such as the name, home address or date of birth of the survey participants was not collected. The names of the hospitals were not recorded in any of the tools. All completed questionnaires and tools were kept securely in a locked filing cabinet. Identifying data such as consent forms were locked in a filing cabinet or carried in a lockable briefcase while working in the field. All electronic data and files relevant to the research were saved on a password protected computer. Nobody apart from the researcher and the supervisors had authorised access to the data.

CHAPTER 5. CHARACTERISTICS OF HOSPITALS

Two zonal hospitals, nine district hospitals and two district-level hospitals (Section 1.5) were selected for this study (Section 4.4). This chapter summarizes the characteristics of these hospitals, focussing on reprocessing of medical devices. Data analysed and discussed in this chapter were collected using the 'Hospital Summary Information' sheet described in sections 4.2.4 and 4.6.4.

5.1 Number of beds

The number of beds in the hospitals varied according to the type of hospital. Zonal Hospitals had the highest number of beds among the hospitals included in the research, with bed numbers varying within each category. The two zonal hospitals selected for this study had bed numbers of 150 and 332. The nine district hospitals had bed numbers ranging from 15 to 60, with an average of 31.The two district-level hospitals had bed numbers of 4 and 5.

5.2 Staffing

For each hospital included in the study, the total number of staff and the number of staff in different categories currently working at the hospital were collected. The categories of the staff working in the hospitals were doctors, nurses, paramedics, support staff and others. The number of staff in total and in each category varied across hospitals as shown in table 5.1.

Of the total staff working in the two zonal hospitals, 42.3% and 27.7% were support staff. District hospitals had percentages of support staff ranging from 20.7% to 38.6%. Similarly, 16% and 14.3% of the total staff working in the two district-level hospitals were support staff. The percentages of support staff were smaller in district-level hospitals compared to higher level hospitals.

The relationship between number of beds and number of total staff working in the hospitals was measured using Spearman's rho correlation coefficient (nonparametric rank correlation). As expected, there was a strong positive correlation between the number of beds and the

number of staff, $r = 0.974$, $n = 13$, $p < 0.001$). This correlation showed that a high number of staff was associated with higher bed numbers in the hospitals.

5.3 Available Clinical Services

Available clinical services in each hospital were documented. All the hospitals provided inpatient services, outpatient services and minor surgical services. However, two of the district hospitals and two district-level hospitals did not provide major surgical services (surgical services requiring an operating theatre). Only zonal hospitals had specialized clinical services. All hospitals except one district-level hospital had emergency services. Dental services were provided by all hospitals except the district-level hospitals. Family planning, immunisation, antenatal services, delivery services and laboratory services were provided by all the hospitals.

Table 5.1: Number of beds and number of staff in different categories working in the hospitals

Hospital Type	Hospital code	Number of beds	Number of staff					
			Doctors	Nursing staff*	Paramedics**	Support staff	Others	Total
Zonal Hospital	02	150	35	42	15	80	17	189
	08	332	73	118	26	114	81	412
District Hospitals	01	15	2	6	6	9	6	29
	03	15	3	16	7	13	5	44
	04	60	8	21	8	18	12	67
	06	36	12	11	5	18	15	61
	07	50	9	16	7	12	14	58
	09	15	5	6	6	9	6	32
	11	25	5	11	5	17	6	44
	12	37	6	16	8	17	15	62
	13	31	6	13	8	13	13	53
District-level Hospitals	05	5	4	8	6	4	3	25
	10	4	1	4	3	2	4	14

** includes staff nurses and auxiliary nurse midwives; ** includes health assistants and auxiliary health workers*

5.4 Reprocessing of Medical Devices

Information about the infrastructure and activities related to the reprocessing of medical devices in the hospitals was collected.

5.4.1 Infrastructure and management

All of the selected hospitals reprocessed and reused medical devices for providing healthcare services to people. Only 6 out of the 13 selected hospitals had a separate area designated for reprocessing of medical devices. These 6 hospitals included 2 zonal hospitals and 4 district hospitals; however, not all the larger district hospitals had a designated area for medical device reprocessing. The remaining seven hospitals did not have any separate designated area. One hospital did not have a hand washing facility in the medical devices reprocessing area. Of the 13 hospitals, 11 hospitals had continuous power supply for the operation of autoclaves, while the remaining two hospitals had about 56 hours and 21 hours per week without power supply for the operation of autoclaves. Only one hospital reported having a budget specific to the reprocessing of medical devices.

5.4.2 Decontamination activities in the hospitals

A number of decontamination activities were being performed in the hospitals included in this study. Such activities included cleaning, chemical disinfection, boiling, steaming and autoclaving. All hospitals performed cleaning, chemical disinfection and autoclaving activities. Three hospitals (i.e. 23%) used glutaraldehyde solution for sterilizing some medical devices such as sharps. Similarly, only three hospitals performed boiling activities. However, the boiling procedure was used only for decontaminating tap water to be used for some surgical procedures (e.g. cesarean section). Only two hospitals performed steaming for decontamination of medical devices which could not withstand autoclaving (e.g. some cannula). An introduction to decontamination activities carried out in the hospitals is given in Section 2.3.

5.4.3 Documents and records

None of the hospitals had policies and standards related to the reprocessing of medical devices. Only 2 out of 13 hospitals had procedure flow charts (non-standardized) for performing moist heat sterilization (autoclaving); both of these hospitals were district hospitals. None of the hospitals had a training manual and training records related to the reprocessing of medical devices. Only one hospital had a participant hand-book for "Infection Prevention and Healthcare Waste Management Training". The hand-book included some sections on decontamination and sterilization along with many other components of infection prevention.

5.4.4 Autoclaves used in the hospitals

The number of autoclaves being used varied among hospitals. Each of the zonal hospitals used two autoclaves while the number of autoclaves being used ranged from 1 to 3 in district hospitals. Each of the district-level hospitals used one autoclave for reprocessing of medical devices.

Of the 24 autoclaves being used at the hospitals, only 3 were downward (gravity) displacement autoclaves (Section 2.4.1.2). All of these were being used by the zonal hospitals. The rest of the autoclaves were basic pressure-cooker type autoclaves. Of the 24 autoclaves, 16 were operated with electricity as the power source while 8 autoclaves were operated with petroleum gas as the power source. The hospitals had purchased 19 of the autoclaves, 4 were reported to be supplied by the Logistics Management Division of the Department of Health Services (Ministry of Health). The remaining autoclave was provided by an external agency.

None of the autoclaves were validated and almost none had spare parts (including gaskets, safety valves and pressure valves) available. Only one autoclave had a spare gasket available. Dates for when the gasket and safety valve were last changed were not known for any autoclaves. Manufacturer's manuals and maintenance records were not available for any of the autoclaves. Incident reports were not available for any of the autoclaves. However, three autoclaves were labelled with instructions for operation by the manufacturers.

5.5 Discussion

5.5.1 Hospital types and reuse of medical devices

The three strata of selected public hospitals represent three different categories of hospital providing different levels of clinical services to the public. The district-level hospitals are the smallest hospitals among the selected hospitals with the smallest numbers of beds and staff. The services these hospitals provide are primary care services with very few inpatient beds and no major surgeries being carried out. However, these hospitals also act as referral hospitals for primary health care service providers such as primary health centres, health posts and sub-health Posts. At district-level hospitals, reusable medical devices were mainly used for minor surgery, dressing of wounds, family planning services, antenatal services and delivery of babies (including uncomplicated and complicated vaginal deliveries).

The district hospitals are larger than the district-level hospitals in terms of the number of beds and the number of staff. These hospitals provide primary care services including dental services, and some surgery requiring a separate operating theatre (e.g. cesarean section, appendicectomy, herniorrhaphy/hernioplasty and cystolithotomy). These hospitals are also referral sites for primary health centres, health posts and sub-health posts. Because of the larger size (in comparison to the district-level hospitals) and a wider range of existing healthcare activities including some major surgeries, these hospitals are likely to use a higher number of reusable medical devices.

The zonal hospitals are the largest among all the hospitals included in this study. These hospitals are secondary care hospitals carrying out some major surgery (within an operating theatre) and providing some specialized clinical services including paediatrics, gynaecology, general medicine, eye care, dermatology, orthopaedics, otorhinolaryngology (ENT) and psychiatry (Department of Health Services - Ministry of Health - Government of Nepal, 2016). These are the referral hospitals for the district-level hospitals and district hospitals. These hospitals are likely to use a much larger number of reusable medical devices in comparison to the district and the district-level hospitals. However, this study did not quantify the reusable medical devices used in the hospitals as this study is primarily aimed at

understanding the medical device reprocessing in the hospitals and it was not practically feasible due to the additional requirements of resources and time.

5.5.2 Staff for medical device reprocessing

Support staff, rather than medical or nursing staff, are most commonly involved in decontamination activities, including cleaning and autoclaving, in the hospitals (sections 7.2.2 and 7.2.5). Though the percentages of support staff were higher in the zonal hospitals than in the lower level hospitals, it was not clear what percentage of these staff were involved in medical device reprocessing activities. A higher percentage of support staff does not guarantee that proper reprocessing and decontamination activities are taking place in the hospitals. The education, training, knowledge, attitudes and practice of support staff towards reprocessing and reuse of medical devices are discussed in chapters 7 and 8.

5.5.3 Infrastructure for medical device reprocessing

Of the thirteen hospitals, six (46%) had a separate area dedicated for reprocessing of medical devices. The remaining hospitals carried out reprocessing activities in areas which were not designated for reprocessing (e.g. patient examination room, general store and corridor). Reprocessing of medical devices requires a dedicated area with a dirty to clean work flow. The fact that fewer than half the hospitals had a dedicated space for reprocessing (e.g. sterile services department, SSD) suggests that lower priority is given by these hospitals to reprocessing of medical devices. Both the zonal hospitals where major surgeries were performed had a dedicated space for reprocessing of medical devices. Of the 7 district hospitals which performed major surgeries (i.e. had an operating theatre), only 3 had a dedicated space for medical device reprocessing. On the other hand, of the 2 district hospitals which did not perform major surgeries, one had a dedicated space for reprocessing of medical devices. Neither of the district-level hospitals had a dedicated area for reprocessing of medical devices. Different guidelines emphasize the importance of central sterilization units in healthcare facilities to sterilize the reusable medical devices in a quality-assured manner (Rutala *et al.*, 2008; WHO, 2016a). The WHO (2016a, p. 30) highlights the importance of an SSD in healthcare facilities as:

> Medical devices processed outside the SSD cannot be controlled and are considered unsafe unless these processes are under the supervision of highly-trained staff of a similar calibre to those in the SSD.

Even the hospitals which had separate designated areas for reprocessing of medical devices did not meet the basic requirements of an SSD. Such requirements include physically separated areas for reception of used medical devices, cleaning, sterilization, cooling and storage, and a clear unidirectional dirty to clean workflow (WHO, 2016a). Though there are no guidelines specific to reprocessing of medical devices in Nepal, some other related guidelines and documents identify the requirement of SSD in public hospitals in Nepal (Ministry of Health and Population - Government of Nepal, 2014b; Ministry of Health and Population - Government of Nepal, 2015a).

5.5.4 Decontamination activities in the hospitals

All of the hospitals were dependent on steam under pressure (autoclaving) for sterilization and reuse of medical devices. Alternative approaches like steaming and chemical sterilization (using a glutaraldehyde solution) were used by few hospitals, and only for some medical devices (usually those which could not withstand a high temperature inside an autoclave). This showed that autoclaving was the key process for sterilizing medical devices in primary care and secondary care public hospitals in Nepal. Understanding the effectiveness of such a key process is crucial for ensuring sterility of medical devices.

5.5.5 Guiding documents for medical device reprocessing

A dearth of policies and guiding documents related to reprocessing of medical devices was observed in all the hospitals. The lack of any guiding documents means that reprocessing activities are carried out at hospitals based on the intuition of staff. Medical device reprocessing is a highly specialized area with empirically established norms and procedures. Performing these procedures without any stringent guidance leads to inconsistency in sterilization processes. The only guiding document (found in only one district hospital) was a participant handbook for “Infection Prevention and Healthcare Waste Management Training” with some sections providing instructions for cleaning, disinfection and sterilization of

medical devices. This document is based on the Reference Manual for Infection Prevention and Healthcare Waste Management published by NHTC under the Ministry of Health and Population providing guidance on reprocessing of medical devices.

5.5.6 Sterilization equipment

About 90% (21 out of 24) of the autoclaves used in these hospitals were basic pressure-cooker type (upward-displacement) autoclaves. These types of autoclave are the most primitive types, and are less effective than downward displacement and pre-vacuum autoclaves in killing microorganisms (Huys, 2010; McDonnell & Sheard, 2012; Perkins, 1956). These autoclaves have poor air displacement capabilities and are usually meant to be used for non-porous loads under strict monitoring of the process using parametric, chemical and biological indicators (McDonnell & Sheard, 2012). This means that almost all of the primary and secondary care hospitals in Nepal are dependent on the most basic types of autoclaves for sterilization of reusable medical devices. Zonal hospitals (secondary care hospitals) had gravity displacement autoclaves, which also are not considered as good as pre-vacuum autoclaves in terms of air removal capabilities. None of the hospitals had autoclaves which could run pre-vacuum sterilization cycles. It is important to evaluate the effectiveness of these autoclaves because they are more likely to show poorer performance than modern autoclaves (e.g. pre-vacuum autoclaves). The scenario is different in other countries. Wai-Kwok and Chi-Ming (2007) reported that 68% of the private dental practices in Hong Kong were using gravity displacement steam autoclaves and 23% of them were using pre-vacuum autoclaves. In Northern Ireland, only 6% (out of 111) of general practices had a benchtop vacuum sterilizer whereas 76% of the practices possessed a benchtop non-vacuum sterilizer (Smyth *et al.*, 1999). Similarly, out of 49 university health services in the UK, only 13 had a vacuum sterilizer (McNally *et al.*, 2001). However, it is noteworthy that none of these studies reported any use of pressure-cooker type (upward displacement) autoclaves.

Both electricity and liquefied petroleum (LPG) gas were used as power sources for heating water inside autoclaves. In some cases, autoclaves meant to be used with electricity were operated using LPG gas. Only two hospitals reported time without power supply every week. Available power supply at the locality could be one of the factors influencing the selection and purchase of autoclaves by the hospitals. However, autoclaves were not always purchased

by the hospitals. Some of them were supplied by the Department of Health Services, and one of them was donated by an external agency. In a situation where an autoclave is not purchased by a hospital itself, the requirements of the hospital specific to the autoclave may not be fulfilled.

Routine maintenance, periodic validation and trouble-shooting are crucial for effective functioning of any biomedical equipment. Those processes were nonexistent for the autoclaves being used in the hospitals in Nepal. Unavailability of spare parts indicates the possibility of interruption in the supply of sterilized medical devices in the hospitals. Moreover, staff were operating autoclaves on their own intuition, as manufacturer's instructions were not available for most of the autoclaves.

In summary, the primary care hospitals (district-level hospitals and district hospitals) and the secondary care hospitals (zonal hospitals) carry out clinical activities which require reprocessing and reusing medical devices. Moist-heat sterilization (autoclaving) is a major technique used for sterilizing medical devices in these hospitals. Hospitals do not have adequate infrastructure and documentation related to reprocessing of medical devices as defined in international guidelines and standards. The hospitals use primitive autoclaves which require regular testing and validation, but this is not being done. This is likely to result in failures of steam sterilization cycles i.e. inability of steam sterilization cycles to achieve the required level of sterility of medical devices.

CHAPTER 6. EFFECTIVENESS OF STEAM STERILIZATION

This chapter summarizes the findings of the testing (i.e. measurement of effectiveness) of 189 steam sterilization cycles with ProSpore2 biological indicator, class 5 chemical indicator and class 1 chemical indicator (sections 4.2.1 and 4.6.1). Pressure recordings of the sterilization cycles (Section 4.6.1) also are analysed and discussed in this chapter. In addition, findings of a Logistic Regression Model for complex samples determining the factors associated with ineffective steam sterilization are presented in this chapter.

6.1 Results of Biological Indicator Tests

A total of 189 steam sterilization (autoclave) cycles (Table 4.1) was tested using ProSpore2 biological indicators (containing 1.3×10^6 spores of *Geobacillus stearothermophilus*). The proportion of steam sterilization cycles showing positive (i.e. rejected) results with the biological indicators was 71.0% (95% CI 46.8% - 87.2%; SE 9.5%). A positive result indicated that not all the spores contained in an indicator tube had been killed, which represents a failure of sterilization. The proportions of positive results for three different hospital types are given in Table 6.1. Examples of biological indicators showing positive (yellow) and negative (purple) results in one of the hospitals are shown in Figure 6.1.

Figure 6.1: Biological indicators showing positive (yellow) and negative (purple) results

Table 6.1: Proportion of autoclave cycles giving positive results with biological indicators

Hospital type	Number of hospitals studied	Estimate	Standard Error	95% Confidence Interval	
				Lower	Upper
Zonal Hospital	2	66.7%	29.8%	9.1%	97.5%
District Hospital	9	66.7%	12.3%	36.8%	87.3%
District-level Hospital	2	90.0%	9.4%	47.0%	98.9%

Because of the complex design of the sample (Section 4.3), an adjustment to the usual Chi-squared test used for analysing contingency tables from data collected by a simple random sample was required. *IBM SPSS Statistics 24* provides an adjusted F statistic which is a variant of the second-order Rao-Scott adjusted chi-square statistic (Rao & Scott, 1981). Although the percentages of autoclave cycles giving positive (failed) biological results varied widely across the three hospital types, these were not statistically significantly different (Adjusted F=0.68, p= 0.51).

The proportion of positive biological indicator results for each of the 13 hospitals was also calculated using Generalized Linear Models in *IBM SPSS Statistics 24*, and a 95% CI was calculated for each hospital. However, it was not possible to produce confidence intervals using the models for the hospitals showing a positive result proportion of 0% or 100%. For these hospitals, 95% CIs were obtained using 'The Rule of Three' a method for calculating the probability of an event that has not yet occurred after a finite number of observations, recommended by Hanley and Lippman-Hand (1983). As shown in Figure 6.4, only one district hospital had a positive result proportion of 0% (95% CI 0% - 20%) whereas 4 hospitals (1 zonal, 2 district and 1 district-level) had a positive result proportion of 100% (95% CI for zonal hospital 75.0% - 100.0% and 95% CI for district and district-level hospitals 80.0% - 100.0%).

6.2 Results of Class 5 Chemical Indicator Tests

Of 189 autoclave cycles tested, 69.8% (95% CI 44.4% - 87.0%; SE 10.1%) showed 'reject' results with class 5 chemical indicators (ProChem SSW Steam Integrator). The rejection proportions for the three levels of hospitals are given in Table 6.2. Figure 6.2 shows examples of class 5 chemical indicators with 'accept' and 'reject' results.

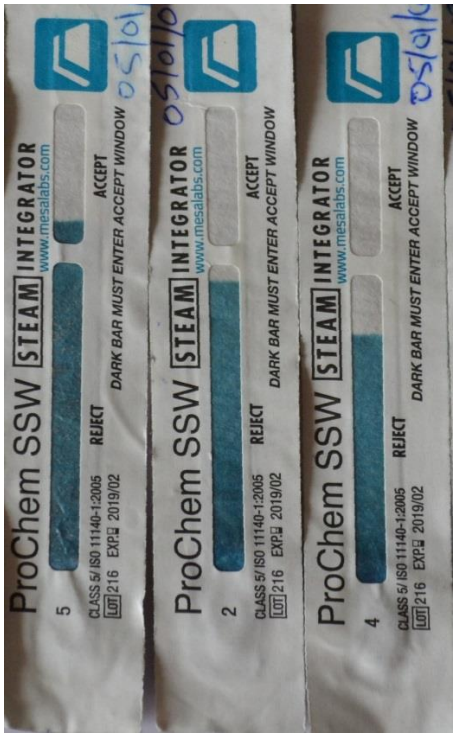

Figure 6.2: Class 5 chemical indicators showing accept (left) and reject (middle and right) results

Table 6.2: Proportion of autoclave cycles giving 'rejected' results with class 5 chemical indicators

Hospital type	Number of hospitals studied	Estimate	Standard Error	95% Confidence Interval	
				Lower	Upper
Zonal Hospital	2	62.5%	33.5%	6.4%	97.6%
District Hospital	9	68.1%	12.4%	37.6%	88.4%
District-level Hospital	2	80.0%	18.7%	22.8%	98.2%

This difference in rejection proportions across levels of hospitals was not statistically significant (Adjusted F = 0.14, p = 0.87).

The rejection proportion for each of the 13 hospitals was calculated following the same procedure as for the calculation of positive biological result proportions (Figure 6.4). Five hospitals (1 zonal hospital, 3 district hospitals and 1 district-level hospital) showed a rejection proportion of 100% (95% CI for zonal Hospital 75.0% - 100.0% and 95% CI for the remaining 4 hospitals 80.0% - 100.0%). None of the hospitals had a rejection proportion of 0% with the class 5 chemical indicator.

6.2.1 Class 5 chemical indicator versus bilogical indicators

Results of class 5 chemical indicators were cross-tabulated with the results of biological indicators (Table 6.3). There was a significant association between the results of the biological and the class 5 chemical indicators (Adjusted F = 173.05, p < 0.001). Of the autoclave cycles with positive (rejected) biological test results, 95.3% (95% CI 81.0% - 99.0%) also showed 'reject' results with the class 5 chemical indicators – this reflected the sensitivity of the chemical indicator i.e. the ability of the chemical indicator to correctly identify those rejected by the biological indicator test. Similarly, of the autoclave cycles with negative (accepted) biological test results, 92.6% (95% CI 84.3% - 96.7%) also showed 'accept' results with the class 5 chemical indicators – this was due to the specificity of the chemical indicator i.e. the ability of the chemical indicator to correctly identify those accepted by the biological indicator test.

Table 6.3: Cross-tabulation of biological and class 5 chemical indicator test results

Class 5 chemical indicator		**Biological indicator**	
		Rejected	**Accepted**
Rejected	Estimate (% within biological indicator)	95.3%	7.4%
	95% Confidence Interval	81.0% - 99.0%	3.3% - 15.7%
	Standard Error	3.1%	2.6%
Accepted	Estimate (% within biological indicator)	4.7%	92.6%
	95% Confidence Interval	1.0% - 19.0%	84.3% - 96.7%
	Standard Error	3.1%	2.6%

It is noteworthy that for 3 of the 13 hospitals, the failure rates shown by class 5 chemical indicators were higher than the rates shown by biological indictors though the biological indicators are considered as the "gold standard" for measuring the effectiveness of steam sterilization cycles (Figure 6.4).

6.3 Results of Autoclave Tape (Class 1 Chemical Indicator)

Overall, 13.5% (95% CI 2.9% – 45.1%; SE 8.7%) of the sterilization cycles did not show a change in colour of the autoclave tape (i.e. black stripes did not appear) after completion of the sterilization cycle. Table 6.4 provides the proportions of autoclave cycles not showing a change in tape colour for the three different hospitals levels. The difference in proportions across the three hospital types was not statistically significant (Adjusted F = 0.46, p = 0.62). Figure 6.3 is an example of autoclave tape showing a change in tape colour (i.e. appearance of black strips) after an exposure to a steam sterilization cycle.

Figure 6.3: An autoclave tape showing black strips after a steam sterilization cycle

Table 6.4: Proportions of autoclave cycles NOT showing a change in colour of an autoclave tape

Hospital type	Number of hospitals studied	Estimate	Standard Error	95% Confidence Interval	
				Lower	Upper
Zonal Hospital	2	0.0%	*	0.0%	12.5
District Hospital	9	11.9%	10.2%	1.5%	54.3%
District-level Hospital	2	26.7%	24.9%	2.1%	86.2%

** cannot be calculated*

The proportion of cycles not showing a change in colour (rejection) was calculated for each of the 13 hospitals following the same procedure as for the calculation of positive biological result proportions (Figure 6.4). The proportion was 0.0% for 10 hospitals i.e. 100% of the autoclave cycles in these hospitals showed a change in colour of the tape (24 cycles in the two zonal hospitals; 105 cycles in seven district hospitals, and 15 cycles in one district-level hospital). In one district hospital, 100% (95% CI 80% - 100%) of the autoclave cycles did not show a change in tape colour.

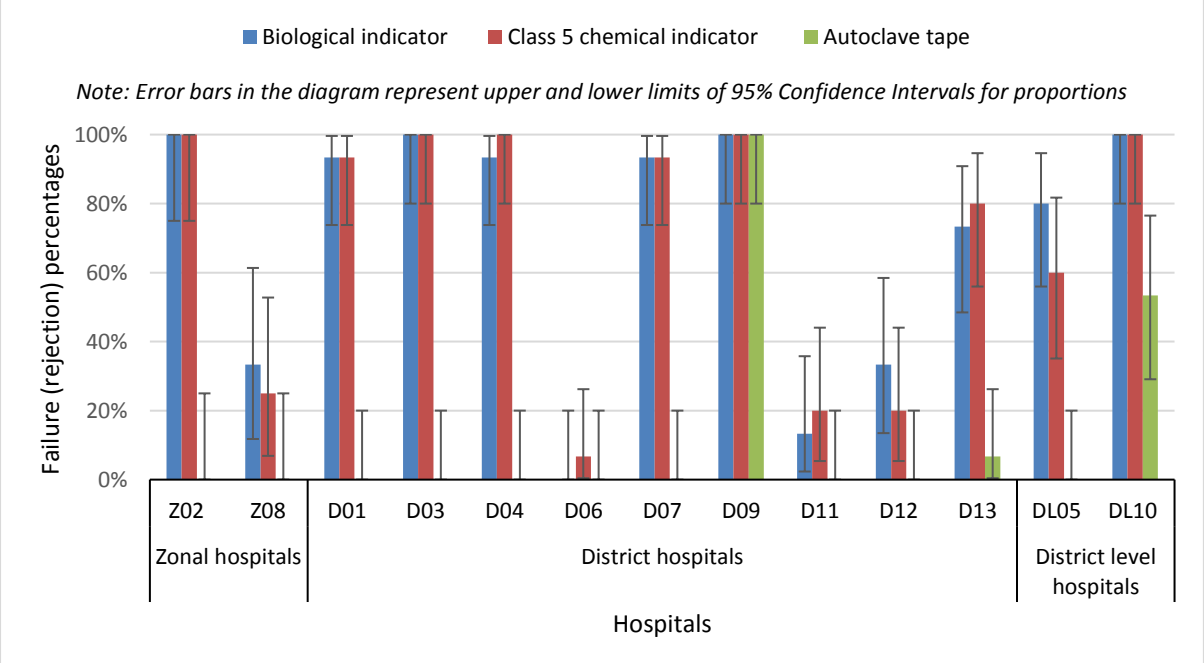

Figure 6.4: Autoclave failure proportions as shown by three different indicators

6.3.1 Autoclave tape versus biological and class 5 chemical indicators

The results of the autoclave tape were cross-tabulated with the results of the class 5 chemical indicators and the biological indicators separately (Tables 6.5 and 6.6). A Chi-square test for independence indicated no statistically significant association between the results of the autoclave tape and the results of the biological indicator (Adjusted F = 1.23, p = 0.29). Similarly, no statistically significant association was found between the results of chemical indicators and the results of autoclave tape (Adjusted F = 1.38, p = 0.27). Of the autoclave cycles with positive (rejected) biological test results, 19.0% also showed 'reject' (i.e. colour not changed) results with the autoclave tape – this was the sensitivity of the autoclave tape i.e. the ability of the autoclave tape to correctly identify those rejected by the biological indicator test. However, of the autoclave cycles with negative (accepted) biological test results, 100.0% showed 'accept' (i.e. colour changed) results with the autoclave tape – this was the specificity of the autoclave tape i.e. the ability of the autoclave tape to correctly identify those accepted by the biological indicator test. Similar findings were obtained when comparing the results of the autoclave tape with the results of the class 5 chemical indicators (Table 6.6).

Table 6.5: Cross-tabulation of autoclave tape and biological indicator test results

Autoclave tape		**Biological indicator**	
		Rejected	**Accepted**
Rejected	Estimate (% within biological indicator)	19.0%	-
	95% Confidence Interval	4.2% - 55.7%	-
	Standard Error	8.7%	-
Accepted	Estimate (% within biological indicator)	81.0%	100.0%
	95% Confidence Interval	44.3% - 95.8%	100.0% - 100.0%
	Standard Error	8.7%	0.0%

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Table 6.6: Cross-tabulation of autoclave tape and class 5 chemical indicator test results

Autoclave tape		Class 5 chemical indicator	
		Rejected	**Accepted**
Rejected	Estimate (% within biological indicator)	19.3%	-
	95% Confidence Interval	4.4% - 55.7%	-
	Standard Error	11.6%	-
Accepted	Estimate (% within biological indicator)	80.7%	100.0%
	95% Confidence Interval	44.3% - 95.6%	100.0% - 100.0%
	Standard Error	11.6%	0.0%

6.4 Pressures inside Autoclave during Sterilization

Readings of the autoclave pressure gauges were to be recorded every minute during each of 189 steam sterilization cycles. However, 4 of the 22 autoclaves tested (i.e. 18.2%) had faulty pressure gauges which did not show any changes in pressures. All of these four autoclaves with faulty pressure gauges were found in three district hospitals, one of the district hospitals having two autoclaves with faulty gauges. Therefore, pressures could not be recorded for 15.5% (95% CI 4.0% - 44.9%) of the sterilization cycles (Table 6.7). For the remaining sterilization cycles, pressures achieved inside the autoclaves during the holding periods (described in Section 2.4) varied between sterilization cycles. The proportion of sterilization cycles achieving a pressure of ≥15 psi during the holding period was 45.9% (95% CI 24.1% - 69.4%), while about 11% of the sterilization cycles had a pressure of < 10 psi during the holding period.

Table 6.7: Pressures achieved during the holding periods of sterilization cycles

Achieved pressures	Estimated Proportion	Standard Error	95% Confidence Interval	
			Lower	Upper
Could not be recorded	15.5%	8.8%	4.0%	44.9%
≥15 psi	45.9%	11.0%	24.1%	69.4%
≥10 psi and<15	27.6%	3.9%	19.9%	37.1%
< 10 psi	10.9%	6.0%	3.0%	32.8%

Figure 6.5 shows pressure curves of three different representative autoclave cycles with three different pressures achieved during the holding period; the different colours of the curves represent different levels of holding period pressure achieved shown in table 6.7.

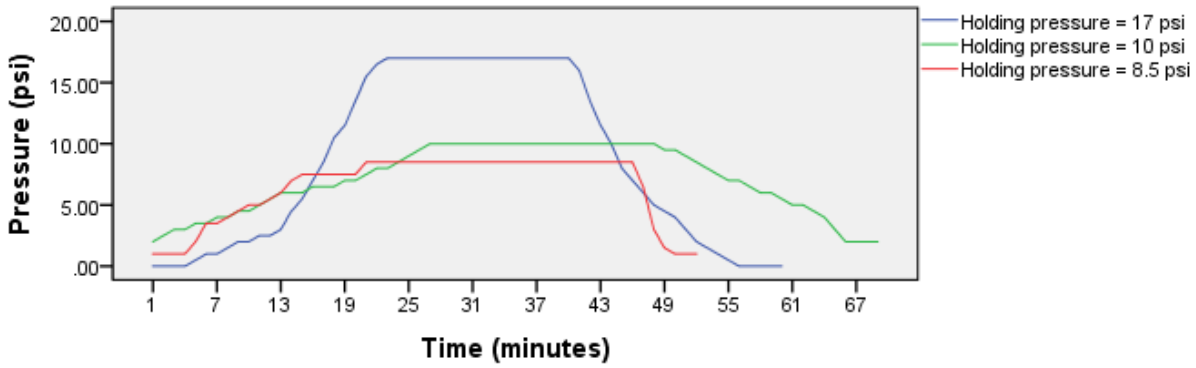

Figure 6.5: Representative autoclave pressure curves showing varying holding period pressures

Pressure readings of autoclave cycles were also cross tabulated with hospital types (Table 6.8). The difference in proportions of pressure readings across hospital types was statistically significant (Adjusted F = 4.73; p = 0.02).

Table 6.8: Pressures achieved during the holding period of autoclave cycles

Hospital type	**< 10 psi** *proportion (95% CI)*	**≥10 and <15 psi** *proportion (95% CI)*	**≥15 psi** *proportion (95% CI)*
Zonal Hospital	12.5% (1.4% - 58.2%)	41.7% (4.4% - 91.7%)	45.8% (2.1% - 97.1%)
District Hospital	15.1% (3.1% - 50.0%)	11.3% (4.2% - 27.0%)	73.6% (39.4% - 92.3%)
District-level Hospital	6.7% (0.8% - 40%)	93.3% (60.0% - 99.2%)	0.0% (0.0% - 10%)

Not all the sterilization cycles had holding periods with a sustained pressure (i.e. plateau phase). Some sterilization cycles had holding periods with pressures intermittently dropping down to lower values, i.e. the holding periods had uneven pressures. 73.2 % (95% CI 39.9% - 91.8%; SE 12.5%) of the sterilization cycles had holding periods with a plateau phase, while the remaining cycles had holding periods with uneven pressure (Table 6.9).

Table 6.9: Maintenance of pressure during the holding periods of sterilization cycles

Holding period pressure	**Estimate**	**Standard Error**	**95% Confidence Interval**	
			Lower	**Upper**
Continuous (plateau)	73.2%	12.5%	39.9%	91.8%
Intermittent (uneven)	26.8%	12.5%	8.2%	60.1%

Figures 6.6 and 6.7 show some examples of pressure curves of autoclave cycles with plateau phase and uneven pressures respectively; different colours of the curves represent different autoclave cycles. Pressure curves of autoclave cycles in each hospital are given in Appendix 24.

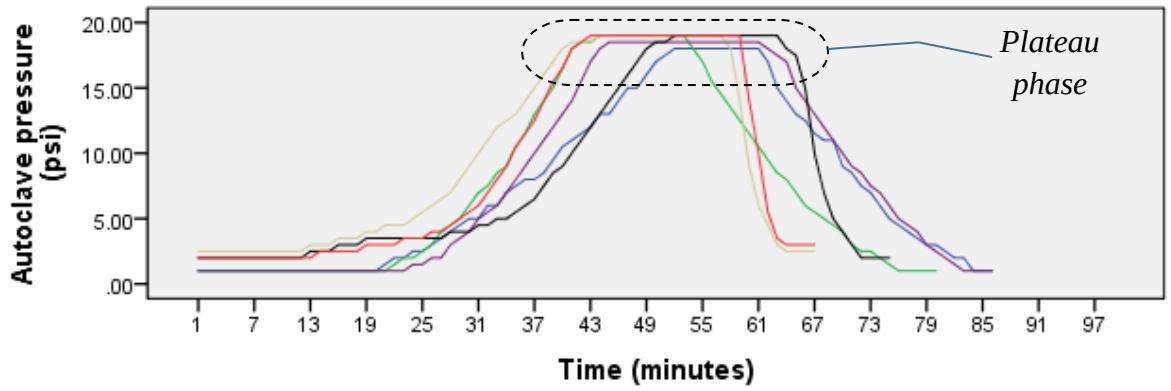

Figure 6.6: Representative autoclave cycle pressure curves with a stable holding period (plateau phase)

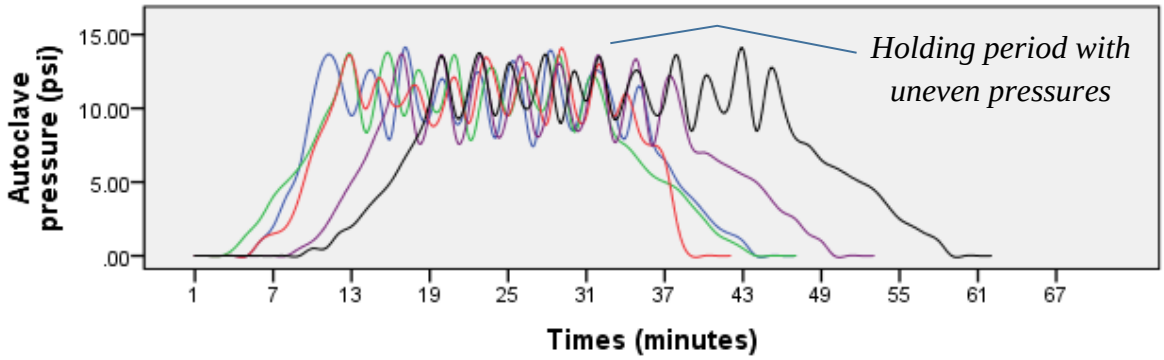

Figure 6.7: Representative autoclave cycle pressure curves with uneven pressures during the holding period.

6.5 Length and Holding Period of Autoclave Cycles

The mean length of an autoclave cycle (the time period between the start and end of the sterilization cycle) was approximately 64.00 min (95% CI 55.80 – 72.56; SE 3.76), whereas the mean holding period was 20.00 min (95% CI 14.29 – 25.70; SE 2.52). The estimated means of the length and holding periods of autoclave cycles for each level of hospital are given in Table 6.10. Figure 6.8 illustrates varying holding periods of autoclave cycles. In addition, both types of holding periods (i.e. with plateau phase and with uneven pressures) were found varying as can be seen in the figures 6.6 and 6.7.

Table 6.10: Estimated means of length and holding period of autoclave cycles

		Estimate Mean (min)	Standard Error	95% Confidence Interval	
				Lower	Upper
Zonal Hospital	Holding period	12.50	4.02	3.39	21.61
	Length of cycle	68.79	9.50	47.62	89.97
District Hospital	Holding period	24.23	2.50	18.57	29.88
	Length of cycle	68.41	5.00	57.26	79.57
District-level Hospital	Holding period	10.87	7.92	0.00	28.78
	Length of cycle	45.47	3.12	38.52	52.41

The relationship between the holding period and the length of the autoclave cycle was examined using the SPSS Complex Samples - General Linear Model procedure. A moderate positive correlation was found between the two variables, r = 0.57, n = 160, p = 0.006. However, the holding periods of autoclave cycles were not statistically significantly associated with hospital type (p = 0.09) nor with the pressures achieved during the holding periods (p = 0.29).

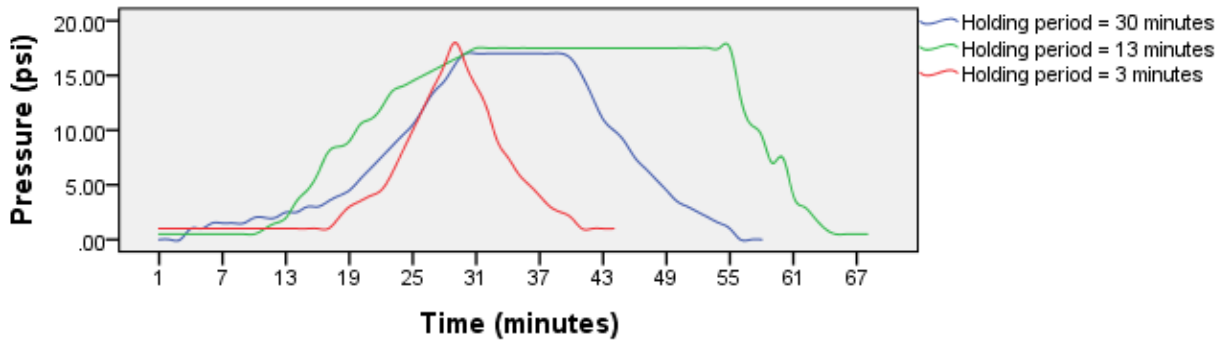

Figure 6.8: Representative autoclave cycle pressure curves showing varying holding periods

6.6 Factors Associated with Ineffectiveness of Moist-heat Sterilization

A logistic regression model for complex samples was used to identify factors associated with steam sterilization failures. The type of autoclave used, pressure achieved during holding period, maintenance of pressure during holding period, duration of holding period (in minutes) and barrier system used (Section 7.2.4) for wrapping medical devices were included in the model. Pressure achieved during holding period and autoclave type were significantly associated with steam sterilization failures when using both biological and class 5 chemical indicators for evaluating effectiveness of sterilization (Table 6.11).

Table 6.11: Complex Samples - Logistic Regression model for sterilization failures

Predictor Variable	Odds Ratio	95% Confidence Interval	P value
Model 1: Biological indicator result – Positive			
Holding period pressure			
≥ 15 psi	0.02	0.00 - 0.75	**0.04**
≥ 10 psi to < 15 psi	0.03	0.002 - 0.42	**0.02**
< 10 psi*	1.00		
Maintenance of pressure			
Continuous	0.66	0.16 - 2.80	0.53
Intermittent*	1.00		
Holding period (minutes)**	0.90	0.81 - 1.00	0.06
Barrier system used			
Combination of two or more systems	2.49	0.31 - 19.96	0.35
Double wrapped, double wrapped container or tray, reusable sterilization container	2.26	0.87 - 5.90	0.09
Single wrapped/pouch*	1.00		
Autoclave type			
Upward displacement (pressure-cooker type)	10.33	2.17 - 49.22	**0.01**
Downward (gravity) displacement*	1.00		
Model 2: Class 5 chemical indicator result – reject			
Holding period pressure			
≥ 15 psi	0.03	0.001 - 0.87	**0.04**
≥ 10 psi to < 15 psi	0.03	0.003 - 0.31	**0.01**
< 10 psi*	1.00		
Maintenance of pressure			
Continuous	1.67	0.37 - 7.56	0.46
Intermittent*	1.00		
Holding period (minutes)**	0.90	0.80 - 1.01	0.07
Barrier system used			
Combination of two or more systems	3.82	0.35 - 41.59	0.24
Double wrapped, double wrapped container or tray, reusable sterilization container	3.45	0.96 -12.40	0.06
Single wrapped/pouch*	1.00		
Autoclave type			
Upward displacement (pressure-cooker type)	23.25	5.30 -101.95	< **0.01**
Downward (gravity) displacement*	1.00		

* Reference category; ** continuous variable

6.7 Discussion

6.7.1 Proportion of steam sterilization failure

The proportion of autoclave cycles showing a positive (failed) result with biological indicators in primary and secondary care hospitals (discussed in Section 1.5) in Nepal is 71.0% (95% CI 46.8% - 87.2%). The globally recommended SAL for reusable medical devices is 10^{-6} i.e. the probability of a product remaining nonsterile after exposing it to a sterilization process should be $\leq 10^{-6}$ (Section 2.4); smaller SAL values such as 10^{-7} indicate better SAL. Level of exposure (i.e. exposure time) to a sterilization process required to achieve an SAL of $\leq 10^{-6}$ is determined conservatively using a reference organism such as spores of *Geobacillus stearothermophilus* (ISO, 2006; ISO, 2009). This means that if an SAL 10^{-6} is achieved after a sterilization process, one out of 1,000,000 products (each of them containing 1,000,000 spores) would remain non-sterile i.e. a 12 log reduction in the number of microorganisms should occur (Section 2.4). A biological indicator containing 1.3×10^6 spores of *Geobacillus stearothermophilus* was used to measure the effectiveness of 189 steam sterilization cycles in the hospitals in Nepal and an overall failure proportion of 71.0% was obtained i.e. 71 of 100 sterilization cycles could not kill all the organisms contained in a biological indicator. Practically, one biological indicator vial was exposed to each of the steam sterilization processes evaluated in the hospitals. Therefore, the failure proportion also means that 71 of 100 biological indicators remained non-sterile after exposure to the sterilization processes in the hospitals. The evaluated sterilization processes were not uniform within and across the hospitals (sections 6.4 and 6.5). Therefore, the overall failure percentage obtained does not directly reflect the SAL achieved in an individual sterilization process in the hospitals. However, given the high sterilization failure proportion in primary and secondary care hospitals in Nepal, the level of sterility of medical devices used in these hospitals is likely to be considerably below the generally accepted target that fewer than 1 in 1,000,000 instruments (or conservatively 1,000,000 biological indicator units) would be nonsterile following sterilization.

The wide 95% CI (46.8% - 87.2%) for the sterilization failure proportion in Nepal reflects considerable variation in failure proportions between the hospitals studied (Figure 1). The failure proportion in Nepal is the highest reported failure proportion of steam sterilization

cycles in different parts of the world. Previous studies have reported steam sterilization failure proportions ranging from 1.5% to 43.0% in different countries using the biological indicator as the measurement tool (see Table 3.1). In all of these earlier studies, participants were provided with biological indicators which were similar to the one used in this study and asked to test the sterilization cycles by themselves. This could have introduced bias i.e. the actual failure proportion could have been higher than the reported failure proportions. All but three of these studies reported steam sterilization failure proportions in dental care facilities. Coulter *et al.* (2001) reported a failure proportion of 2.0% in primary care practices in the UK and Miranzadeh *et al.* (2013) reported a failure proportion of 2.9% in 6 government hospitals in Iran. Similarly, Kelkar *et al.* (2004) reported a failure proportion of 12% in 11 eye care hospitals in India. Evidently, the failure proportion in primary and secondary care hospitals in Nepal is much higher than previously reported failure proportions worldwide. However, it cannot be ignored that the number of bacterial spores contained in the biological indicator has not been reported by most of the previous studies. Biological indicators with smaller number of bacterial spores are likely to give smaller failure proportions because a shorter time period is required to kill a smaller number of spores at a given temperature.

The finding that there was no statistically significant difference in steam sterilization failure proportions between different levels of hospitals in Nepal indicates that secondary care hospitals (zonal hospitals) are not better than primary care hospitals (district and district-level) in terms of sterilization of medical devices. However, the number and the level of surgical activities that require reuse of medical devices are higher in secondary care hospitals (Section 5.5.1). Therefore, harm associated with inadequately sterilized medical devices is likely to be greater in secondary care hospitals than in primary care hospitals. The failure proportions show the need for improvement in the sterilization of medical devices in primary and secondary care public hospitals, irrespective of the levels and ranges of services provided. Zonal Hospitals need to act more urgently to improve the sterilization of medical devices because of likely greater risk (due to higher level surgical procedures) associated with inadequately sterilized medical devices.

Variation of sterilization failure proportions among hospitals indicates that there are some hospitals which are performing comparatively better than other hospitals in terms of sterilization of medical devices. However, 69% (i.e. 9 of 13) of the hospitals had failure proportions of over 70% indicating an urgent need for improvement. Only 1 of 13 hospitals

had a failure proportion of 0%. It is important to understand the differences in the sterilization practices between the hospital with no sterilization failures and the other hospitals showing higher failure proportions. This will help replicate good practices from the hospitals showing good sterilization results to the hospitals showing poor results. Differences in practices between the hospitals are discussed later in this chapter (sections 6.7.3 and 6.7.4) and in Chapter 7 (Section 7.3).

6.7.2 Performance of chemical indicators

As with the biological indicator, a high proportion (69.8%) of steam sterilization cycles showed failed ('reject') results with the class 5 chemical indicator. In a previous multicentre pilot study conducted in 7 low- and middle-income countries (LMICs) including Nepal, 90 autoclave cycles in 9 hospitals were tested using class 5 chemical indicators. Of the 90 tested cycles, 5.6% showed unacceptable ('reject') results (O'Hara *et al.*, 2015). Six of the hospitals participating in the study were tertiary care hospitals and all of the autoclaves included in the study were pre-vacuum autoclaves. The chemical indicators were provided to surgeons from 26 hospitals in 9 LMICs participating in a scientific conference, who were asked to test the single most frequently used autoclave in their surgical departments. Only 9 of 26 hospitals returned the chemical indicators after testing. There was a possibility that only those who obtained favourable results returned the chemical indicators after testing. In fact, as reported by the study, one of the hospitals did not return the used chemical indicators because of unfavourable results. On the other hand, this study was carried out in primary and secondary care hospitals and none of the autoclaves tested were pre-vacuum; the autoclaves tested were either gravity displacement or simple pressure-cooker type autoclaves. The recommended temperature and time for the autoclaves tested in the study reported here (a minimum of 15 minute exposure time at 121°C) and the previous multicentre pilot study (4 minute exposure time at 132°C -135.5°C) were also different. These differences between the two studies could have led to the difference in the proportion of sterilization failures in these studies.

Ideally, class 5 chemical indicators are expected to have performance equivalent to biological indicators for detecting success or failure of steam sterilization cycles (Kirckof, Kshirsagar & Bennaars-Eiden, 2009; McDonnell & Sheard, 2012). Schneider *et al.* (2005) found a statistically significantly higher ($p < 0.05$) failure (rejection) rate with biological indicators

than with class 5 chemical indicators when tested in failure (sub-optimal) conditions. Their findings demonstrated that the sterilization indicators may perform differently in in-use sterilization conditions compared with ideal conditions, and that sterilization indicators may differ in the level of information they provide regarding the effectiveness of the sterilization process. Therefore, it was important to know the performance of class 5 chemical indicator in the settings of primary and secondary care hospitals in Nepal. The rejection proportions shown by the class 5 chemical indicator were slightly lower than the rejection proportions shown by the biological indicator in 3 of the 13 hospitals (Figure 6.4). On the other hand, though the biological indicators are considered "gold standard" for measuring effectiveness of a steam sterilization cycle, the rejection proportions shown by the class 5 chemical indicator were slightly higher than the rejection proportions shown by the biological indicator in 4 of the 13 hospitals. For the remaining 6 hospitals, both the indicators showed equal rejection proportions. Indeed, altogether, the results demonstrated a statistically significant association between the results of the biological and class 5 chemical indicators in these settings ($p < 0.001$). This association could be because of very poor rather than sub-optimal or optimal sterilization conditions in most of the hospitals. This finding along with the sensitivity and specificity (95.3% and 92.6% respectively) of the class 5 chemical indicator will be very important when decisions are made about selecting an appropriate indicator for routine monitoring of steam sterilization processes in these settings. In addition, ease of use and cost of the indicators will also need to be considered when making such decisions. Chemical indicators are considerably cheaper than biological indicators. For the indicators used in this study, the price of the class 5 chemical indicator was about NZ$ 67 (Nepalese Rupees 4,800) per 100 tests whereas the price of biological indicator was about NZ$ 812 (Nepalese Rupees 57,760) per 100 tests. Chemical indicators are easy to interpret and the results are obtained immediately after sterilization.

The results of the autoclave tape (class 1 chemical indicator) were statistically significantly different from those of the biological indicator and class 5 chemical indicator (Figure 1). The proportion of autoclave cycles not showing a change in colour of the autoclave tape was smaller (13.5%) than the proportions showing positive or reject results with the biological and class 5 chemical indicators (71.0% and 69.8%). Indeed, only three hospitals had autoclave cycles not showing a change in colour of the autoclave tape (Figure 6.4). As discussed in Section 4.2.1, principally, autoclave tape is affixed to each pack of medical devices before sterilization. It helps determine whether a package is exposed to a sterilization

process. However, it doesn't inform us about the effectiveness of sterilization process. To obtain a change in the colour of an autoclave tape, the sterilization process does not need to be necessarily adequate. Therefore, the difference in the results of the autoclave tape and the other indicators (biological and class 5 chemical) was not unexpected. Indeed, it was surprising that 13.5% of the autoclave cycles were unable to change the colour of the autoclave tape. Medical devices obtained from these cycles could be considered equivalent to medical devices unexposed to any sterilization process.

6.7.3 Maintenance of pressure during sterilization

The pressure required to achieve the temperature (121°C) recommended for the types of autoclaves used in these hospitals is 15 psi above atmospheric pressure. This temperature and pressure is also recommended by the 'Reference Manual for Infection Prevention and Healthcare Waste Management', which is the only national document providing some guidance on moist-heat sterilization (NHTC - Ministry of Health and Population - Government of Nepal, 2015b). However, pressures achieved during the holding period varied greatly between autoclave cycles. Fewer than half (45.9%) of the sterilization cycles achieved the recommended pressure (Table 6.7). This meant that fewer than 45.9% of the sterilization cycles could achieve the temperature of 121°C. About 11% of the sterilization cycles could not even achieve a pressure of 10 psi. Temperature is one of the key variables determining the success or failure of a steam-sterilization process. These findings help to explain the high failure proportion of steam-sterilization in the primary and secondary care hospitals in Nepal. However, temperature alone cannot determine the success or failure of a steam sterilization cycle. Other variables including holding/exposure period (time), steam quality and packaging of medical devices will also determine the success or failure of a sterilization cycle. All these variables need to be taken into account when identifying factors associated with the effectiveness of steam sterilization cycles in the settings of the primary and secondary care hospitals in Nepal. Such analysis is described in sections 6.6 and 6.7.5.

In about 27% of the steam sterilization cycles, the pressures achieved during the holding periods were not uniform (sustained) throughout the holding periods (Table 6.9). The pressures fluctuated during the holding period (Figure 6.4). Such a fluctuation in pressure was caused by an intermittent and automatic release of the steam from the pressure control

valve of the autoclave. In this situation, as the sterilizing temperature is dependent on the pressure inside the autoclave, theoretically, the temperature also fluctuates intermittently. In general, it is recommended to maintain a uniform temperature/pressure during a holding period of a sterilization cycle. Huys (1999) reported that steam pulsing (intermittent release and admission of steam) before holding period improves the air removal process and thus the performance of the autoclave. However, the fluctuations observed in this study were during the holding period of the sterilization cycle. Therefore, it is important to understand the association of pressure fluctuation with the effectiveness of sterilization cycles. An analysis looking at such association is done in sections 6.6 and 6.7.5.

6.7.4 Holding period

Sterilizing medical devices effectively or achieving predetermined SAL is not just about achieving a predetermined pressure (15 psi) or temperature (121°C). It is also about ensuring exposure of medical devices to such temperature for a required period of time known as the holding or exposure period. The average holding period for steam sterilization cycles in the primary and secondary hospitals in Nepal was 20 min (95% CI 14.29 – 25.70). The holding period required for achieving SAL of 10^{-6} can be calculated from the D-Value (time to reduce the surviving population by 90% or 1 log10; discussed in Section 2.4) of the indicator organism used for monitoring the sterilization process. As provided by the manufacturer of the biological indicator used in this study, the D-Value of the provided microorganism (*G. stearothermophilus*) for saturated steam at 121°C (i.e. D_{121}-Value) was 1.7 minutes. In this case, for achieving a SAL of 10^{-6} (i.e. 12 log reduction in a number of microorganisms), a holding period of 20.4 (1.7 x 12) minutes is required. D-Values are calculated by manufacturers in an ideal laboratory setting. However, the time required to reduce the surviving population by 90% in hospital settings (in-use settings) may not be the same as the time required in ideal settings. Such time in hospital settings may vary according to the autoclave type (gravity displacement or pre-vacuum), the barrier system used (wrapped or unwrapped), the types of materials to be sterilized, and the steam quality. Indeed, longer exposure periods may be required in in-use settings to achieve the required SAL (Schneider *et al.*, 2005).

Recommended holding periods (for saturated steam at 121°C) for sterilizing medical devices vary in different guidelines and standards. The 'Reference Manual for Infection Prevention and Healthcare Waste Management' recommends a holding period of 20 min for unwrapped medical devices and 30 minutes for wrapped medical devices (NHTC - Ministry of Health and Population - Government of Nepal, 2015b). The CDC has recommended an exposure period of 30 min for sterilizing wrapped medical devices at 121°C (Rutala *et al.*, 2008). The ISO has specified 12 min as the minimum holding time required for sterilizing medical devices at 121°C (ISO, 2006). Likewise, the WHO has not recommended any specific holding time, but rather stated that the contact and/or cycle will vary from 3 to 18 min depending on the sterilization temperature which is121°C-135 °C (WHO, 2016a). It is clear that there is no universal exposure or holding period recommended for sterilizing medical devices at a particular temperature, rather this needs to be validated and defined for a specific setting and a sterilization process. The study reported here showed that no specific holding period was being used for sterilizing medical devices in the hospitals despite a specific holding period having been recommended by the 'Reference Manual for Infection Prevention and Healthcare Waste Management'.

6.7.5 Factors associated with ineffectivene sterilization

In principle, the effectiveness of a steam sterilization process (autoclaving) is determined by the temperature (or pressure) of the autoclave chamber, the holding period, the quality of steam and general qualities of medical device packages including structure, weight, material and sterile barrier system (ISO, 2013; Young, 1997). As described in Section 4.6.1, biological and class 5 chemical indicators were not kept inside the actual packages of medical devices for testing of steam sterilization cycles. The indicators were enclosed in a separate package using a barrier system which was equivalent to the barrier system used for the respective sterilization cycle. In this context, factors likely to be associated with the results of the indicators were the temperature of the autoclave, the holding period, the quality of steam, and the barrier system used. Other qualities of medical devices packages, for example, structure, weight and material, were not likely to affect results of the indicators as the indicator package did not include any medical devices. The temperatures of the autoclave chamber could not be measured; however, the pressure of the chamber was recorded every minute for each sterilization cycle. The temperature of the autoclave is dependent on the

pressure i.e. pressure of autoclave chamber indicates temperature achieved inside the autoclave. Therefore, pressure achieved during holding period was included in the logistic regression model for finding factors associated with sterilization failures. However, the pressure of the autoclave chamber was not consistent during the holding period of all of the sterilization cycles; pressure dropped to a lower level intermittently for some sterilization cycles (Section 6.4). This characteristic of pressure during the holding period was also included in the model. Quality of steam (i.e. whether it is dry, saturated or super-saturated) also could not be measured. However, the type of autoclave is one of the factors determining the quality of steam inside the autoclave. Gravity displacement autoclaves are considered better than pressure-cooker type vertical autoclaves in terms of displacement of dry air with steam (McDonnell & Sheard, 2012) and therefore, the type of autoclave was also included in the analysis. In addition, holding periods (in minutes) and barrier systems used were also considered in the analysis.

All of the above factors will have an influence on the results of the biological and chemical indicators in an ideal condition where all factors act logically. It is important to understand how these factors interact with each other in the settings of primary and secondary hospitals in Nepal, and which factors are statistically significantly associated with the results of the indicators, i.e. with the effectiveness of a sterilization process.

Pressure achieved during the holding period of an autoclave cycle had a statistically significant association with the results of the biological and class 5 chemical indicators (Table 6.11). Autoclave cycles with higher holding period pressures were less likely to give ‘failed’ indicator results i.e. positive biological indicator results and/or ‘reject’ class 5 chemical indicator results. This association is obvious in ideal conditions as well. Higher pressure causes higher temperature inside the autoclave, and higher temperature is more effective in killing microorganisms.

Autoclave type was also associated with the results of the chemical and biological indicators. Sterilization cycles with simple pressure-cooker type autoclaves were more likely to give ‘failed’ results with the indicators compared to the sterilization cycles with downward (gravity) displacement autoclaves. As discussed in Section 2.4.1, gravity displacement autoclaves are better than pressure-cooker type basic autoclaves in terms of displacement of dry air with saturated steam in the sterilization chambers, and hence the likelihood of killing of microorganisms is also greater.

These results indicate a need for achieving recommended pressure (≥ 15 psi) in all of the autoclave cycles for the successful sterilization of medical devices. The results also demonstrate the advantage of gravity displacement autoclaves over pressure-cooker type autoclaves in terms of effectiveness of moist-heat sterilization. It is also noteworthy that the results of both the biological and the class 5 chemical indicators were associated with the holding period pressure and the autoclave type in a statistically similar fashion (Table 6.11).

Although other factors including the holding period, the barrier system used for packaging medical devices, and maintenance of pressure during holding period were not found to be statistically significantly associated with the results of the indicators used, their role in effective sterilization of medical devices cannot be simply ruled out. The apparent dissociation of these factors with the indicator result could have been because of very poor sterilization conditions in most of the hospitals, for example, when sterilizing pressure is below 10 psi, a variation in holding period length is less likely to affect the indicator results. Similar explanations can apply also with the other factors included in the analysis.

In summary, a minimum requirement of achieving 15 psi for steam-sterilization needs to be fulfilled for effective sterilization of medical devices. Only after achieving this, could the association of other factors, including holding periods and barrier systems, with effective sterilization be studied and appropriate recommendations made. On the basis of these results, a recommendation for upgrading autoclaves from basic pressure-cooker type autoclaves to at least gravity displacement autoclaves can be made. However, the effect of gravity displacement cycles inside actual packages of medical devices could not be studied as the indicators were not kept inside the actual packages. On the other hand, none of the autoclave cycles used in primary and secondary care hospitals in Nepal were pre-vacuum sterilization cycles which are normally considered superior to gravity displacement cycles and are recommended by most international standards for sterilization of wrapped packages (ISO, 2006; Rutala *et al.*, 2008; Standards Australia & Standards New Zealand, 2014; WHO, 2016a).

CHAPTER 7. COMPLIANCE WITH RECOMMENDED/STANDARD PRACTICES

A number of audits was carried out in each hospital using an audit tool (described in sections 4.2.3 and 4.6.2). Processes of medical device reprocessing cycles (outlined in Section 2.5) were observed by the researcher and practices were recorded using the audit tool. The characteristics of medical devices reprocessed were also observed and recorded using the audit tool. This chapter summarizes the findings of the audits carried out in the hospitals.

7.1 Characteristics of Medical Devices Reprocessed

For 90.7% (95% CI 78.7% - 96.3%) of the reprocessing cycles, single-use items (examples, gauzes, cotton balls and gloves) were included in the sterilization loads in addition to the reusable medical devices.

Medical devices with different designs and materials were reprocessed. For more than 90.0% of the reprocessing cycles, both metallic and non-metallic medical devices were reprocessed in the hospitals (Table 7.1).

7.2 Compliance with Standard/Recommended Reprocessing Practices

Processes of medical device reprocessing (Section 2.5) took place in a dirty to clean workflow for only 10.1% (95% CI 1.8% - 40.9%) of the reprocessing cycles. Compliance with the recommended practices for each of the processes is described in the sections below.

7.2.1 Transport of used medical devices

For none of the reprocessing cycles, were medical devices transported to the decontamination area using an appropriate container (a rigid, durable, leak-proof container with a tight-fitting lid). However, all of the containers used for transporting used medical devices were easy to clean and disinfect.

Table 7.1: Percentages of reprocessing cycles including different types of medical devices

Characteristics of medical devices	Estimate	Standard Error	95% Confidence Interval	
			Lower	Upper
Designs*				
Solid, hollow	100.0%	0.0%	100.0%	100.0%
Pin and box joints	100.0%	0.0%	100.0%	100.0%
Lumen, tubing	46.4%	5.0%	35.6%	57.6%
Porous	91.9%	3.4%	80.6%	96.9%
Material				
Metal	100.0%	0.0%	100.0%	100.0%
Non-metal	92.4%	3.4%	80.5%	97.3%

* Examples of medical devices with different designs:

Solid, hollow: *bowl, dish, scalpel handle;* ***Pin and box joints:*** *scissors, forceps;* ***Lumen, tubing:*** *urinary catheter, cannulated screws, dental hand piece;* ***Porous:*** *Cotton, gauze, linens*

7.2.2 Cleaning and disinfection

Medical devices were cleaned before sterilization for all of the reprocessing cycles. Support staff (office assistants) were involved in the cleaning of medical devices for 98.4% (95% CI 88.3% - 99.8%) of the reprocessing cycles. Nursing staff were involved in the cleaning of medical devices for only 1.6% (95% CI 0.2% - 11.7%) of the reprocessing cycles. Medical devices were cleaned manually for all of the reprocessing cycles.

Information about time period between use and cleaning of medical devices was obtained for each reprocessing cycle from the staff involved in cleaning medical devices. The estimated average time period between use and cleaning of medical devices was about 298 min (95% CI 101 - 495). For an estimated 27.6% (95% CI 16.2% - 43.0%) of the reprocessing cycles, the time period between use and cleaning of medical devices was about 60 min. For an estimated 19.3% (95% CI 10.4% - 33.0%) of the reprocessing cycles, the time period was

about 120 min. Indeed, the time between use and cleaning of medical devices ranged from about 20 min to about 2880 min (i.e. about 48 h).

Different cleaning agents, including disinfectant solution, detergent/soap solution and plain water, were used in different combinations for manual cleaning of medical devices. Disinfection followed by washing with detergent/soap solution and rinsing with plain was the most commonly used cleaning process (Table 7.2). Enzymatic cleaners were never used for cleaning of medical devices.

Table 7.2: Percentages of reprocessing cycles using different cleaning processes

Cleaning agents used	**Estimate**	**Standard Error**	**95% Confidence Interval**	
			Lower	**Upper**
Disinfectant solution → detergent/soap solution → plain water*	53.6%	10.8%	30.5%	75.3%
Disinfectant solution → detergent/soap solution*	9.3%	8.7%	1.0%	50.5%
Disinfectant solution → plain water*	18.8%	7.3%	7.4%	40.2%
Detergent/soap solution → plain water*	7.1%	5.0%	1.4%	29.6%
Plain water only	11.2%	6.5%	2.9%	35.1%

** the agents were used for cleaning of medical devices in the given sequence*

Though medical devices were cleaned manually before sterilization for all of the reprocessing cycles, recommended practices for cleaning were not always followed. Some practices, including cleaning of lumens with brushes of appropriate size, were non-existent (Table 7.3).

Table 7.3: Percentages of reprocessing cycles following recommended cleaning (and disinfection) practices

Recommended practices	Estimate	Standard Error	95% Confidence Interval	
			Lower	Upper
Medical devices are cleaned before sterilization	100.0%	0.0%	100.0%	100.0%
Used medical devices are soaked in or sprayed with water before cleaning, to prevent drying	81.7% *	7.9%	57.9%	93.5%
Cleaning is done in a separate area from where the instrument will be used (i.e., designated dirty area)	38.1%	11.5%	17.3%	64.5%
Medical devices are pre-disinfected before cleaning (e.g. with hypochlorite solution)	81.7%	7.9%	57.9%	93.5%
Medical devices are opened/dismantled for cleaning purpose	76.4%	10.7%	46.4%	92.4%
Medical devices are submerged in water while washing them manually using a brush	1.0%	1.0%	0.1%	7.6%
For instruments with lumens, all channels are cleaned using cleaning brushes of appropriate size	0.0%	0.0%	0.0%	0.0%
Cleaning brushes are single use (disposable) items	0.0%	0.0%	0.0%	0.0%
After completion of cleaning, reusable brushes are cleaned and either high level disinfected or sterilized	0.0%	0.0%	0.0%	0.0%
Instruments are rinsed thoroughly with water after cleaning	86.6%	9.0%	53.3%	97.3%
Medical devices are dried with low-linting (disposable or reusable) towels immediately after rinsing	19.9%	8.1%	7.4%	43.4%
Enzymatic cleaner, detergent, and/or disinfectant are used according to manufacturer's instructions	68.3%	12.4%	37.7%	88.5%

** medical devices were soaked in hypochlorite solution instead of plain water*

Gloves were the only PPE used by staff during most of the reprocessing cycles (97.9%; 95% CI 93.60% - 99.30%). Eye protection, face masks and protective clothing were rarely used (Table 7.4).

Table 7.4: Percentages of reprocessing cycles for which staff used PPEs during cleaning

	Estimate	Standard Error	95% Confidence Interval	
			Lower	Upper
Eye protection	1.1%	1.0%	0.1%	8.0%
Gloves	97.9%	1.1%	93.6%	99.3%
Protective clothing	4.8%	4.4%	0.6%	30.5%
Facemask	6.4%	5.4%	0.9%	33.7%

7.2.3 Inspection

Medical devices were inspected after cleaning for 30.5% (95% CI 15.6% - 50.9%) of the reprocessing cycles. However, an illuminated magnifier was not used to inspect instruments after cleaning in any of the reprocessing cycles.

7.2.4 Packaging

Different sterile barrier systems were used for packaging medical devices (Table 7.5). The percentages of barrier systems used were statistically significantly different across hospital types ($p = 0.04$).

Linen was used as the wrapping material for all (100%) of the reprocessing cycles which included wrapped medical devices in the sterilization load. The envelope fold wrapping technique was used at all times when medical devices were wrapped.

Hinged devices were opened or devices were dissembled while packing them for only 1.2% (95% CI 0.2% - 8.1%) of the reprocessing cycles. For 28.8% (95% CI 12.5% - 53.5%) of the reprocessing cycles, packages were labelled with the date of sterilization. Similarly, for 8.0% (95% CI 0.9% - 45.0%) of the cycles, packages were labelled with the expiration date. For

none of the reprocessing cycles, were packages labelled with the sterilizer used and the cycle or load number.

Table 7.5: Percentages of reprocessing cycles using different sterile barrier systems for packaging of medical devices

Sterile barrier system used	Estimate	Standard Error	95% Confidence Interval	
			Lower	Upper
Single wrapped/pouch	35.6%	7.4%	21.2%	53.2%
Double wrapped in wrapping material or pouches, double wrapped container or tray, reusable sterilization container	27.8%	6.0%	16.6%	42.8%
Combination of two or more systems	36.6%	9.6%	18.7%	59.1%

7.2.5 Sterilization (autoclaving)

Support staff (office assistants) carried out the autoclaving process for 97.0% (95% CI 87.5% - 99.3%) of the reprocessing cycles. Nursing staff carried out the process for only 3.0% (95% CI 0.7% - 12.5%) of the reprocessing cycles. Table 7.6 shows percentages of reprocessing cycles in which recommended/standard practices for autoclaving were followed. For none of the autoclave cycles, were parameters including cycle/load number, operator, sterilization date and time, pressure, temperature and holding period recorded. Autoclave tape was used for 48.7% (95% CI 29.8% - 68.0%) of the autoclave cycles. However, biological and chemical indicators were used for none of the autoclave cycles. Dry sterilized packages were obtained from only 10% (95% CI 3.6% - 28.5%) of the autoclave cycles.

Table 7.6: Percentages of reprocessing cycles following recommended autoclaving practices

Recommended practices	Estimate	Standard Error	95% Confidence Interval	
			Lower	Upper
Timer is used to monitor holding period of the autoclave cycle	6.4%	2.8%	2.4%	16.1%
Holding period of the autoclave cycle starts when the pressure gauze shows the reading of required pressure (e.g.15 lbs)	18.2%	8.0%	6.3%	42.4%
The following parameters are recorded for each sterilization cycle:				
Cycle/load number	0.0%	0.0%	0.0%	0.0%
Operator	0.0%	0.0%	0.0%	0.0%
Date and time	0.0%	0.0%	0.0%	0.0%
Pressure	0.0%	0.0%	0.0%	0.0%
Temperature	0.0%	0.0%	0.0%	0.0%
Holding period	0.0%	0.0%	0.0%	0.0%
Indicators used for monitoring sterilization process				
Autoclave tape	48.7%	9.0%	29.8%	68.0%
Class 5 chemical indicator	0.0%	0.0%	0.0%	0.0%
Biological indicator	0.0%	0.0%	0.0%	0.0%
Result of autoclave tape is recorded	0.0%	0.0%	0.0%	0.0%
Sterilizer’s physical parameters are reviewed after each run	0.0%	0.0%	0.0%	0.0%
Indicator tape is used on the outside of each wrapped package (for the loads where indicator tape is used)	79.4%	7.8%	57.0%	91.8%
Sterilized packs are intact and dry	10.8%	5.1%	3.6%	28.5%

7.2.6 Transport and storage

The percentages of reprocessing cycles for which standard practices for transport and storage of sterilized packages were followed are given in Table 7.7. Packages that had been processed in the autoclave were not inspected for integrity in any of the reprocessing cycles and compromised packages were not repackaged and reprocessed prior to use.

Table 7.7: Percentages of reprocessing cycles following recommended transport and storage practices

Recommended practices	Estimate	Standard Error	95% Confidence Interval	
			Lower	Upper
Sterilized packages are checked for integrity, and compromised packages are repackaged and re-sterilized before use	0.0%	0.0%	0.0%	0.0%
Sterilized items are transported and delivered in a dry and clean container	47.2%	9.4%	27.8%	67.5%
Sterilized packages are allowed to cool down to room temperature before storage	89.1%	6.8%	63.3%	97.5%
A separate area is allocated for storage of sterilized medical devices	40.9%	6.7%	27.1%	56.3%
Sterilized packages are stored and distributed according to "the first one to enter is the first one to leave"	25.1%	8.9%	10.4%	49.1%
The area for storing sterilized packages is well-ventilated and provides protection against dust, moisture, insects, and temperature and humidity extremes	31.5%	16.5%	7.8%	71.6%

7.3 Percentage Compliance

Mean percentage compliance with standard reprocessing practices was obtained by calculating the mean of the percentage of standard practices followed for a reprocessing cycle by a hospital. Here, the numerator is the number of recommended practices followed and the denominator is the number of applicable practices. The mean percentage compliance for all primary and secondary care hospitals was 25.9% (95% CI 21.0% - 30.8%). The higher the hospital level, the higher was the mean percentage compliance with the standard reprocessing practices (Table 7.8). One-way ANOVA test was performed to determine the difference in the mean percentage compliance between three hospital types and the difference in the mean was found to be statistically significant ($p < 0.01$). In addition to one-way ANOVA test, a pairwise multiple comparison test (*Tamhane's T2*, an one-way ANOVA post hoc test) was performed to determine the difference in the mean between each pair of hospital types (IBM Knowledge Center, 2017). The means were statistically significantly different ($p < 0.01$) between each pair of hospital types (i.e. between zonal hospital and district hospital, between district hospital and district-level hospital, and between district-level hospital and zonal hospital). Sample design was ignored to perform one-way ANOVA test and Tamhane's T2 test as these could not be performed for complex samples using *IBM SPSS Statistics 24*.

Table 7.8: Mean percentage compliance with standard reprocessing practices for hospital levels

Hospital type	Percentage Estimate	Standard Error	95% Confidence Interval	
			Lower	Upper
Zonal hospital	32.0%	0.1%	31.8%	32.1%
District hospital	26.6%	3.0%	19.9%	33.4%
District-level Hospital	19.6%	0.1%	19.4%	19.7%

Mean percentage compliance for each of the core processes of reprocessing cycle were calculated for each hospital type and also for overall hospitals (Table 7.9). Comparatively, hospitals were more compliant with recommendations for cleaning and disinfection, and storage and use of medical devices. However, compliance with these processes was also below 50%.

Table 7.9: Mean percentage compliance for core processes of a reprocessing cycle

Core processes of reprocessing cycle	Hospital types	Percentage Compliance	Standard Error	95% Confidence Interval	
				Lower	Upper
Transport of used devices	**All hospitals**	**26.1%**	**5.6%**	**13.7%**	**38.5%**
	Zonal hospitals	27.3%	17.7%	0.0%	66.8%
	District hospitals	23.4%	6.4%	9.0%	37.7%
	District-level hospitals	35.7%	7.2%	19.8%	51.7%
Cleaning and disinfection	**All hospitals**	**45.8%**	**2.2%**	**40.8%**	**50.7%**
	Zonal hospitals	54.6%	3.2%	47.5%	61.8%
	District hospitals	46.5%	3.0%	39.9%	53.2%
	District-level hospitals	37.8%	1.5%	34.5%	41.0%
Inspection and packaging	**All hospitals**	**10.9%**	**2.3%**	**5.7%**	**16.1%**
	Zonal hospitals	19.8%	6.2%	6.0%	33.5%
	District hospitals	12.3%	3.1%	5.4%	19.2%
	District-level hospitals	0.0%	0.0%	0.0%	0.0%
Sterilization (autoclaving)	**All hospitals**	**9.0%**	**1.5%**	**5.7%**	**12.3%**
	Zonal hospitals	11.1%	0.3%	10.5%	11.6%
	District hospitals	10.2%	1.9%	6.0%	14.4%
	District-level hospitals	2.9%	2.8%	0.0%	9.1%
Transport and storage	**All hospitals**	**39.3%**	**5.5%**	**27.0%**	**51.6%**
	Zonal hospitals	43.9%	4.2%	34.5%	53.3%
	District hospitals	37.9%	7.7%	20.7%	55.1%
	District-level hospitals	42.3%	2.2%	37.3%	47.2%

In addition, the mean percentage compliance for each hospital included in the study was calculated. Mean percentage compliances for the two zonal hospitals were similar. The percentage compliances for district hospitals ranged from 14.7% to 46.0%, showing considerable variation in practices across the hospitals. On the other hand, the two district level hospitals had similar average compliances (Figure 7.1).

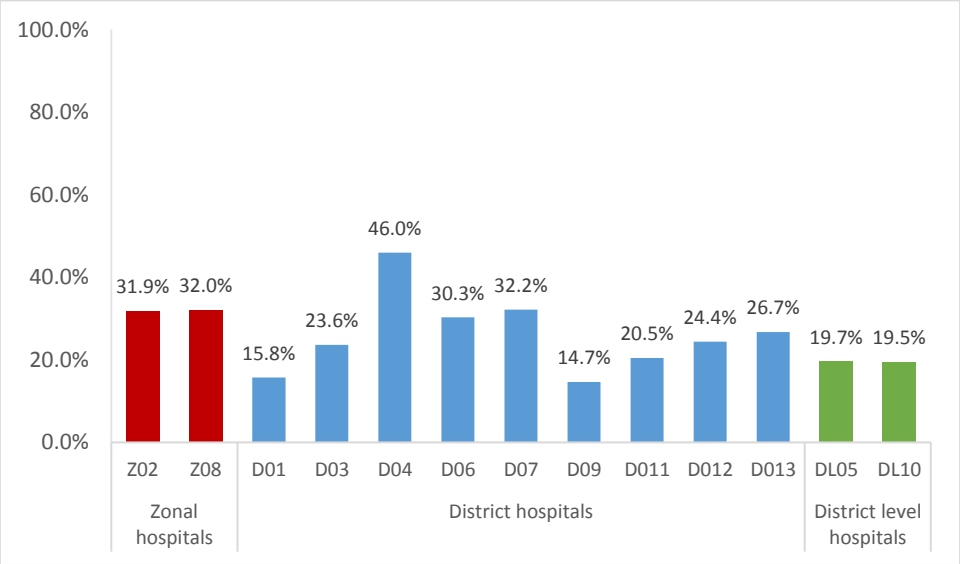

Figure 7.1: The mean percentage compliance (for each hospital) with recommended practices for core processes of reprocessing cycle

7.4 Quality of Water

Table 7.10 provides average pH and hardness values for water used for cleaning used medical devices in the hospitals. The average water pH used for cleaning medical devices ranged from 6.48 (slightly acidic) to 8.05 (basic).The average hardness of water ranged from 5.93 mg/L $CaCo_3$ to 402.50 mg/L $CaCo_3$ (Table 7.10).

Table 7.10: pH and hardness of water used for cleaning of medical devices in the hospitals

Hospital type	Hospital Code	pH	Hardness (mg/L $CaCo_3$)
Zonal hospitals	02	7.73	402.50
	08	6.88	143.33
District hospitals	01	6.75	179.33
	03	8.05	167.00
	04	6.72	5.93
	06	6.48	51.93
	07	6.88	115.67
	09	6.52	99.67
	11	7.25	121.80
	12	7.27	152.33
	13	7.40	160.33
District-level hospitals	05	7.47	147.00
	10	6.60	104.13

7.5 Discussion

This study focused primarily on sterilization and reuse of reusable medical devices. However, most (90.7%) of the moist-heat reprocessing cycles also included single-use items in the sterilization loads along with the reusable medical devices. Indeed, those single use items were not necessarily previously used single-use items rather they were unused and unsterilized single-use items included in the sterilization loads for their subsequent use in clinical procedures. Such items included cotton gauzes and cotton balls. However, there were some instances where previously used single-use items, for example, gloves, were also included in the sterilization loads for further reuse. Results described in this chapter are normally about sterilization of reusable medical devices. However, the inclusion of single-use items in sterilization loads will also be mentioned occasionally as this can have an effect on sterilization of all medical devices in a sterilization load.

7.5.1 Dirty to clean work flow

In Chapter 5 (Section 5.4.1), it was shown that about 50% of the hospitals did not have a separate designated area for reprocessing of medical devices and none of the hospitals had physically separated areas for reception of used medical devices, cleaning, sterilization, cooling and storage. Such an inadequate infrastructure does not support a dirty to clean workflow for reprocessing of medical devices. For about 90% of the reprocessing cycles in the hospitals, decontamination activities did not take place in a dirty to clean workflow. However, poor understanding and implementation of the dirty to clean workflow in the hospitals could have adversely affected the establishment of an SSD with separated areas for reception of used medical devices, cleaning, sterilization, cooling and storage.

7.5.2 Design of medical devices

According to ISO/TS 17665-3, the design of medical devices is important for specifying steam sterilization requirements as resistance to steam penetration is design dependent (ISO, 2013). This is because the air in all cavities and spaces within medical devices needs to be replaced with steam for proper sterilization. All of the reprocessing cycles in the hospitals included solid, hollow medical devices (for example, bowls) for which air is easily displaced by steam, and the orientation of the medical device doesn't affect the displacement of air. However, medical devices with pin and box joints (for example, scissors and forceps) need to be in an open position to allow contact with the steam on all surfaces. The practice of opening devices with pin and box joints in the hospitals will be discussed in Section 7.5.6. About 92% of the reprocessing cycles had sterilization loads with porous items such as linen and cotton. More than 46% of the cycles had loads including items with lumen or tubing, such as dental hand pieces and laparoscopic sheaths. Air removal is more difficult with such items and active air removal is usually recommended for ensuring the attainment of sterilizing conditions. Indeed, none of the steam sterilization processes used by primary and secondary care hospitals in Nepal had an active air removal process such as pre-vacuuming. No specific sterilization processes were designated for medical devices having specific designs, and devices with different designs were included in a single load. Such practice in the absence of an active air removal process is detrimental to the achievement of sterilizing conditions within the sterilization load.

7.5.3 Transportation of used medical devices

Safe transportation of used medical devices is important to minimise microbial contamination of the surrounding environment, and also to minimise the risk of device-associated infection among healthcare worker and patients. A rigid, durable, leak-proof container with a tight fitting lid is recommended for transportation of used medical devices to the decontamination area (WHO, 2016a). However, for all of the reprocessing cycles in the hospitals in Nepal, used medical devices were either transported in an inappropriate container or transported without using a container. Such an inappropriate handling practice is putting healthcare workers and patients at risk of injuries and/or exposure to microorganisms.

7.5.4 Cleaning and disinfection

For all of the reprocessing cycles, medical devices were cleaned after use before the sterilization process. However, cleaning was done in a designated dirty area for only 38.1% of the reprocessing cycles. Cleaning of medical devices in areas where other activities such as hand washing, dish washing, food preparation and drinking are performed, poses a risk of contamination of other areas and thus increases the risk of transmission of microorganisms to healthcare workers and patients. The risk of transmission of microorganisms was further amplified by the practice of cleaning medical devices without submerging them in water. For only 1% of the reprocessing cycles, were medical devices submerged in water while being cleaned. Washing medical devices without submerging them in water may create splashes and aerosols which can also increase inhalation of disinfectant by the cleaners and contact of mucous membranes with the disinfectant.

7.5.4.1 Use of PPE during cleaning process

The risk of infection among healthcare workers was further increased by very poor compliance with the recommended use of PPEs. Gloves were used by the healthcare workers during cleaning for most (about 98%) of the reprocessing cycles. Use of eye protection (1.1%), protective clothing (4.8%) and facemasks (6.4%) by healthcare workers during cleaning process was rare (see Table 7.4). Bagg *et al.* (2007) reported the use of gloves by 99% of staff in general dental practices in Scotland while the percentages of staff not using

eye protection, face mask and waterproof overalls during cleaning were 51%, 57% and 93% respectively. A study conducted in one of the largest hospitals in Nepal found that 20.9 % of "non-professional staff", 19.2% of nurses, 5.6% of laboratory workers and 3.1% of doctors had evidence of past or present HBV infection (Shrestha & Bhattarai, 2006). The authors of the study claimed that higher occurrence of HBV among "non-professional staff" and nurses was because of the lack of adequate HBV vaccination and their involvement in the cleaning of medical devices without proper measures to protect themselves. Findings of the study reported here also support the claim made by Shrestha and Bhattarai (2006). For more than 98% of the reprocessing cycles, support staff were involved in the cleaning of medical devices.

7.5.4.2 Manual cleaning and its effectiveness

Medical devices were cleaned manually for all of the reprocessing cycles in all of the hospitals. Automated washers are commonly used in many countries for cleaning of reusable medical devices, but studies have found that both manual and automated cleaning processes are effective in reducing the microbial load on medical devices if executed properly (Alfa *et al.*, 2006; de Souza Evangelista *et al.*, 2015). Manual cleaning processes are more prone to human factors compared to automated processes. Ofstead *et al.* (2010) found adherence to endoscope reprocessing guidelines for 1.4% of endoscopes reprocessed manually, and for 75.4% of endoscopes reprocessed with an automated endoscope cleaner and reprocessor. There was variation in manual cleaning practices in the hospitals of Nepal as well. The cleaning process varied from single-step cleaning using plain water to three-step cleaning using disinfectant, detergent/soap and plain water (see Table 7.2). For 9.3% of the reprocessing cycles, the cleaning process did not include final rinsing with water after washing with detergent solution. For 11.2% of the reprocessing cycles, the cleaning process included washing with plain water only. Such suboptimal cleaning processes are not effective for removing microorganisms from the medical devices. Variabilities in manual cleaning processes in general dental practices in Scotland were also reported by Bagg *et al.* (2007). The Reference Manual for Infection Prevention and Healthcare Waste Management recommends a three-step manual cleaning process for hospitals in Nepal. However, this cleaning process needs to be audited and validated to ensure effective and reproducible cleaning of medical devices.

Cleaning of medical devices is a critical step for reprocessing of medical devices, as it significantly reduces bioburden on the surfaces of medical devices (de Souza Evangelista *et al.*, 2015). However, this is not as simple as it may appear. Staff responsible for cleaning of medical devices need to have a clear understanding of microorganisms and the importance of cleaning in medical device reprocessing. Seavey (2009) highlights the need for educating staff involved in reprocessing activities at least in the areas of basic medical terminology, human anatomy and physiology, microbiology, infection prevention and control, regulations and standards, surgical instruments, and all processes of reprocessing cycles. In an ideal context, monitoring of cleaning process using a validated scientific monitoring technique is recommended for ensuring adequate cleaning of medical devices (Alfa, 2013). However, support staff (office assistants) were involved in the cleaning of medical devices for almost all (98.4 %) of the reprocessing cycles in the primary and secondary care hospitals. The low level of education of these staff is discussed in Chapter 8 (Section 8.1.3); some of these staff were even illiterate. A required level of cleaning of medical devices is unlikely to be achieved without having properly trained and educated staff for reprocessing of medical devices.

7.5.4.3 Pre-disinfection of medical devices

For about 82% of the reprocessing cycles in Nepal, the cleaning process included pre-soaking of medical devices in hypochlorite solution (usually Calcium Hypochlorite). The 'Reference Manual for Infection Prevention and Healthcare Waste Management' also recommends pre-soaking of medical devices in hypochlorite solution before cleaning the devices with soapy water and then plain water. However, the medical devices were not always cleaned with a soap/detergent solution and plain water following pre-soaking in hypochlorite solution (Table 7.2). For about 19% of the total reprocessing cycles, medical devices were soaked in hypochlorite solution followed by cleaning with plain water only, while for 9.3% of the reprocessing cycles medical devices were soaked in hypochlorite solution followed by cleaning with a soap/detergent solution only. According to Huys (2010), in some other countries such as France, medical devices are soaked in disinfectant to reduce bioburden before cleaning. Recommendations for soaking medical devices in hypochlorite solutions were made in some guidelines during the rise of the HIV pandemic. Such recommendations were made for the safer handling of medical devices by staff during manual cleaning (Angle, Cole & Murphy, 1989; Tietjen, Bossemeyer & McIntosh, 2003; WHO, 1988). The practice of

soaking medical devices in hypochlorite solution is likely to have been adopted around the same time in Nepal as well. Acharya (2003) wrote an editorial in a national medical journal in Nepal about the importance of pre-soaking medical devices in disinfectants to protect healthcare workers, especially those involved in the cleaning of medical devices, from HIV. In the absence of proper and consistent use of PPEs (discussed in Section 7.5.4.1), this practice might have provided some protection to the staff handling used medical devices, however, the practice of pre-soaking could have deterred staff from the proper and consistent use of PPEs. This possibility needs further exploration. Recent international guidelines and standards do not recommend pre-soaking of medical devices in a disinfectant solution before cleaning (Rutala *et al.*, 2008; Standards Australia & Standards New Zealand, 2014; WHO, 2016a). WHO has put forward the following reasons for no longer recommending the pre-soaking practice (WHO, 2016a, p. 45) :

1. It may damage/corrode the instruments
2. The disinfectant may be inactivated by blood and body fluids, which could become a source of microbial contamination and formation of biofilm
3. Transportation of contaminated items soaked in chemical disinfectant to the decontamination area may pose a risk to health-care workers and result in inappropriate handling and accidental damage
4. May contribute to the development of antimicrobial resistance to disinfectants

With proper and consistent use of PPEs, and centralised medical device reprocessing, the practice of pre-soaking medical devices in hypochlorite solution is not required for health care facilities in Nepal. For 68.3% of the reprocessing cycles including a pre-soaking procedure, hypochlorite solution was not used according to manufacturer's instructions – this increases the likelihood of corrosion of medical devices with the solution. Avoiding use of hypochlorite solution with medical devices can also be a cost-saving approach as it prevents corrosion of instruments and thus prolongs the durability of instruments. In addition, use of hypochlorite solution at the point of patient care seems to be unfavourable for establishing centralized reprocessing services in hospitals because transportation of used medical devices while being immersed in the solution is unsafe and difficult.

It is crucial to prevent drying of blood, tissue, faeces or sputum, on medical devices before cleaning because these can make the cleaning process much more difficult (Rutala *et al.*, 2008). When pre-soaking in hypochlorite solution is avoided, drying of blood, tissue, faeces

or sputum on medical devices is likely to occur in Nepal as this study found that the duration of the use and cleaning of medical devices varied across reprocessing cycles, 30 min to 3 h being the range of duration for most of the reprocessing cycles. However, the duration was up to 48 h for some reprocessing cycles, therefore, the practices of cleaning medical devices immediately after the procedure (usually within one hour) or keeping medical devices moist until cleaning are crucial for effective cleaning of medical devices and the prevention of formation of biofilms on medical devices (Roberts, 2013).

7.5.5 Inspection

Medical devices were inspected visually after cleaning for only 30.5% of the reprocessing cycles. Inspections are carried out to verify the effectiveness of the cleaning process in removing all blood, tissue, faeces or sputum from all surfaces of the medical devices. Use of a magnifier or similar inspection devices was non-existent in the hospitals. This finding indicates that the process of verifying cleanliness and functionality of cleaned medical devices was either non-existent or very poor in the hospitals in Nepal.

7.5.6 Packaging

Packaging provides a barrier to microorganisms and moisture for maintaining the sterility of medical devices. On the other hand, packaging also presents a barrier to the sterilizing agent (steam) by providing resistance to it reaching all surfaces of the medical devices. Therefore, it is very important to develop a validated packaging (or barrier) system for sterilization of medical devices in hospitals so that sterility of medical devices can be achieved without allowing the entry of microorganisms to the sterile packages. Barrier systems used for reprocessing of medical devices in the hospitals in Nepal included single wrapping in linen (35.6%), double wrapping in linen or keeping inside a reusable sterilization container (27.8%), and the combination of two or more systems (36.6%). None of these barrier systems were validated for effective sterilization. Additionally, the same autoclaves and sterilization processes were used for sterilizing packages with different barrier systems. The effects of such barrier systems on the ability of a sterilization process to kill microorganisms have been discussed in Section 6.7.5. In general, wrapped medical devices are meant to be sterilized

using a pre-vacuum sterilization cycle (Huys, 2010). It was noteworthy that primary care hospitals used more complex barrier systems compared to secondary care hospitals.

For all the reprocessing cycles sterilizing wrapped medical devices, linens were used as the wrapping material. Previous studies have demonstrated the effectiveness of linens in maintaining sterility of wrapped medical packages (Barrett, Stevens & Taranter, 2003; Bhumisirikul, Bhumisirikul & Pongchairerks, 2003). However, any wrapping material needs to be evaluated in terms of various characteristics including barrier effectiveness, sterilant penetrability, ease of use, puncture resistance, toxicity, linting, cost, drapeability and disposal (Rutala & Weber, 2000). Currently, there are various options available for packaging of medical devices including rigid containers, peel pouches (plastic and/or paper), and woven and nonwoven wrapping materials. Packaging materials other than linens could be cost-effective and easier for some medical devices. Such options also need to be explored and used by hospitals for continuous improvement in medical device reprocessing.
Another important consideration to be made while packaging medical devices is the opening of hinged medical devices or dissembling of complex medical devices according to manufacturer's instructions. Opening or dissembling of medical devices allows steam to reach all the surfaces of medical devices to be sterilized. Indeed, for only 1.2% of the reprocessing cycles, were hinged devices opened or devices dissembled. Therefore, for most of the hinged or complex medical devices sterilized, not all surfaces were exposed to steam and likely to be sterilized. As discussed in Section 7.5.2, all of the reprocessing cycles included medical devices with pin and box joints.

7.5.7 Sterilization

Most of the standard practices for sterilization (autoclaving) were not followed for most of the reprocessing cycles. No chemical or biological indicators were used to monitor the effectiveness of sterilization, except for the use of indicator tape for fewer than 50% of the reprocessing cycles. Indeed, autoclave tapes are not designed to measure the effectiveness of autoclave cycles; they only indicate an exposure of a package of medical devices to a sterilization process (Proietti, 1997). Additionally, none of the sterilization cycles had variable parameters (time, temperature and pressure) recorded. This showed that medical devices were being reused without having concrete evidence to indicate the sterility of

medical devices. Information such as load number, operator, and sterilization date and time were also not recorded. In the case of an incident (such as SSI) likely to be associated with medical devices, it was difficult to trace the sterilization load, person sterilizing the load, or the date and time of sterilization. This indicated that it was unlikely that the possible source of infection would be identified, thus preventing correction of faulty practices.

For only 10.8% of the sterilization cycles, were sterilized packages found to be dry. For the remaining sterilization cycles, sterilized packages were wet or contained moisture. The wet sterilized packages could have been associated with one or more factors including quality of packaging material, packaging technique, loading technique, sterilization process, sterilizer, steam quality and storage area (Basu, 2017). Moisture can facilitate the entrance of microorganisms to the sterilized packages. In general, wet sterilized packages are considered as contaminated, and re-sterilized before use, and wet sterilized porous loads such as textiles can be even more problematic (Huys, 2010). Some studies conducted in Nepal have shown that different microorganisms including *S. aureus*, *Micrococcus* spp., coagulase-negative staphylococci, *Bacillus* spp., *Pseudomonas* spp., *Acinetobacter* spp. and yeasts exist in hospital indoor environments (Pradhan & Shrestha, 2013; Sapkota *et al.*, 2016). In these settings where sterile storage conditions are not controlled, the chances of contamination of wet packages with microorganisms could be high. None of the wet sterilized packages were subjected to re-sterilization in the hospitals in Nepal. There is a need for a thorough assessment to establish the causes of wet sterilized packages in order to formulate recommendations for solving the problem.

7.5.8 Transport and storage of sterilized packages

The absence of routine inspection of packages after sterilization for integrity was observed in all of the hospitals. The absence of inspection of sterilized packages is also linked with the practice of not re-sterilizing wet sterilized packages discussed above. Sterilized packages were delivered in a dry and clean container for fewer than half of the reprocessing cycles. Separate areas for storage of sterilized packages were allocated for only 41% of the reprocessing cycles and, of the separate areas allocated for storage, only 31.5% were well-ventilated providing protection against dust, moisture, insects, and temperature and humidity

extremes. These gaps in the storage of sterilized packages do not favour long-term sterility of medical devices, which is further compromised by wetness of sterilized packages.

7.5.9 Percentage compliance

The mean percentage compliance with standard/recommended practices for the reprocessing of reusable medical devices achieved by all the primary and secondary care hospitals was only 25.9% (see Table 8). There is no standard cut-off value for percentage compliance with these practices. Ideally, hospitals should follow all standard/recommended practices for ensuring sterility of medical devices. In this sense, the mean percentage compliance with reprocessing practices is poor. Higher level hospitals achieved higher average percentage compliance, which is to be expected as higher level hospitals are likely to have higher level staff and better infrastructure. The mean percentage compliances of the three hospital levels for each of the core processes of the reprocessing cycle were also calculated, and higher level hospitals again had higher mean compliance for each of the core processes, except transport of used medical devices (see Table 7.9). Overall, hospitals had comparatively better compliance with recommendations for cleaning and disinfection, and transport and storage (after sterilization) of medical devices. Compliance with recommendations for transport of used medical devices, inspection and packaging, and sterilization was very poor.

7.5.10 Quality of water for reprocessing

The average pH of water used for reprocessing of medical devices in the hospitals ranged from 6.52 to 8.05. This pH range falls within the typical pH range of potable water and is considered acceptable for cleaning of medical devices (Lyon, 2008). McDonnell and Sheard (2012) recommended pH between 6.0 and 9.0 as appropriate for cleaning, disinfection and rinsing of medical devices and also for generating steam for sterilization of medical devices. Lyon (2008) recommended a similar pH range (6.5 to 8.5) for cleaning of medical devices. However, Lyon recommended deionized water for steam generation.

The average total hardness of water varied considerably across hospitals ranging from 5.93 mg/L to 402.50 mg/L $CaCO_3$. Most of the hospitals were supplied with “hard” water, i.e. water having total hardness $\geq$ 120 mg/L $CaCO_3$. Recommendations made by different

guidelines and authors for water hardness for cleaning medical devices also differ to some extent. The Australian/New Zealand Standard (AS/NZS 4187:2014) recommends using water with total hardness ≤ 60 mg/L $CaCO_3$ (Standards Australia & Standards New Zealand, 2014), whereas some authors have recommended a threshold of 150 mg/L $CaCO_3$ (Lyon, 2008; McDonnell & Sheard, 2012). More than 38% of the hospitals had an average total hardness of water >150 mg/L $CaCO_3$. This indicated that water in those hospitals was not ideal for cleaning medical devices. Hard water causes white deposits or scale (e.g. calcium carbonate, $CaCO_3$) on medical devices. Such deposits are difficult to remove with water (because of their low solubility; $CaCO_3$ water solubility = 15 mg/L at 25°C) and can cause clogging of devices, spotting on devices, and ultimate device damage; the deposits also provide a matrix for bacterial adhesion/growth. In addition, hard water can also inactivate soaps used for cleaning, leading to poor cleaning of medical devices.

Water is not only required for the cleaning process of medical device reprocessing cycles; it is needed for generating steam for the steam sterilization (autoclaving) process. As with the recommended water hardness for cleaning of medical devices, the recommended hardness level for feed-water for generating steam also differs between guidelines/authors. McDonnell and Sheard (2012) consider a water hardness level of < 20mg/L $CaCO_3$ as an acceptable level for steam generation whereas some documents recommend using only treated water for generation of steam (Department of Health-UK, 2016; Lyon, 2008). Such water treatments may include softening, purification (reverse osmosis, deionization or distillation), and degassing. None of the hospitals used treated water for use in autoclaves and only one hospital had a water supply with an average total hardness level of < 20mg/L $CaCO_3$. Hospitals with hard water need to treat the water (at least softening) for using with the autoclaves. Bigger hospitals, for example zonal hospitals, may need to have an appropriate water treatment plant for obtaining water for steam generation.

In addition to having damaging effects on medical devices, hard water can also cause damage to the electric heating system of an autoclave. The hard water deposits accumulate gradually on the surface of an electric heating coil and form a thick layer around it. Such a layer of deposits can significantly decrease the heating efficiency of the coil and can significantly increase the length of an autoclave cycle (Lyon, 2008). Figure 7.2 (picture taken in one of the hospitals included in this study) shows a heating coil of an autoclave covered with a layer of deposits (most likely to be caused by hard water) and a newly purchased heating coil.

Figure 7.2: A water-heating coil covered with a layer of deposits (most likely to be CaCO3 from hard water) and a newly purchased heating coil

CHAPTER 8. KNOWLEDGE AND ATTITUDES OF HEALTHCARE WORKERS

This chapter will describe and discuss the results of a survey of healthcare workers (including autoclave operators) about their knowledge and attitudes towards sterilization and reuse of medical devices.

The survey was conducted in district-level, district and zonal hospitals from June 2016 through December 2016. The hospitals included in the survey were the same hospitals (n = 13) which were selected for the measurement of the effectiveness of steam sterilization. A total of 234 questionnaires was distributed to the healthcare workers working in the selected hospitals (Section 4.5). Of these, 219 (93.6 %) healthcare workers returned completed questionnaires to the researcher. Of the 219 healthcare workers, 92.2% (n = 202) completed the questionnaire on their own and returned it to the researcher, 7.8% (n = 17) of the healthcare workers could not complete the questionnaire on their own and hence, the researcher conducted interviews with them and completed the questionnaire. All of the interviewed healthcare workers were office assistants.

8.1 Demographic Information

8.1.1 Gender

The proportion of female healthcare workers participating in the survey was higher than the proportion of male healthcare workers (Table 8.1). Of the total participants, 63.9% (n = 140) were female and 36.1% (n = 79) were male.

Table 8.1: Proportion of male and female healthcare workers participating in the survey

Gender	Number (Percentage)
Male	79 (36.1)
Female	140 (63.9)
Total	**219 (100)**

8.1.2 Age

The age of the healthcare workers participating in the survey ranged from 18 to 59 years with an average of 32 years and a standard deviation of ±9.5 (Table 8.2). More than 55% of the participants were aged ≤ 30 years. A more detailed breakdown of the age of participants is presented in Appendix 25.

Table 8.2: Age of survey participants: range, mean and standard deviation

	N	Minimum	Maximum	Mean	SD
Age in years	218	18	59	32.32	±9.50

8.1.3 Healthcare education

The qualifications of the healthcare workers participating in the survey were in medicine, surgery, nursing, dental hygiene or paramedical healthcare. A number of participants had some years of school education whereas some of them had no formal education at all. Table 8.3 summarizes the highest educational qualifications in healthcare possessed by the survey participants.

Table 8.3: Summary of qualifications of the survey participants

Educational qualifications in healthcare	Number (Percentage)
Master's Degree (Medicine or Surgery)	13 (5.9)
Master's Degree (Nursing)	2 (0.9)
Bachelor's Degree (Medicine and/or Surgery)	34 (15.5)
Bachelor's Degree (Nursing)	25 (11.4)
Certificate in Health	14 (6.4)
Certificate in Nursing	36 (16.4)
Certificate in Dental Hygiene	2 (0.9)
Community Medical Auxiliary (Auxiliary Health Worker)	22 (10.0)
Auxiliary Nurse Midwife	54 (24.7)
School education*[1]	12 (5.5)
No formal education[1]	5 (2.3)
Total	**219 (100.0)**

** Some respondents had not completed school education; they had completed different years in school (i.e. classes such as 5, 7, 8); [1] These two categories belong to autoclave operators.*

8.1.4 Healthcare profession

Of the total survey participants, nurses comprised the highest proportion and office assistants comprised the lowest proportion (Table 8.4). Doctors and paramedics were also included in the survey.

Table 8.4: Professional categories of healthcare staff participating in the survey

Profession	Number (Percentage)
Doctors	47 (21.5)
Nurses	117 (53.4)
Paramedics	38 (17.3)
Office Assistants (Autoclave Operators)	17 (7.8)
Total	**219 (100.0)**

8.1.5 Duration of work in healthcare

The study participants had from 2 months to 39 years (mean = 9.7 years, SD = 9.7) of work experience in healthcare. Figure 8.1 shows the participants' years of work experience in health care.

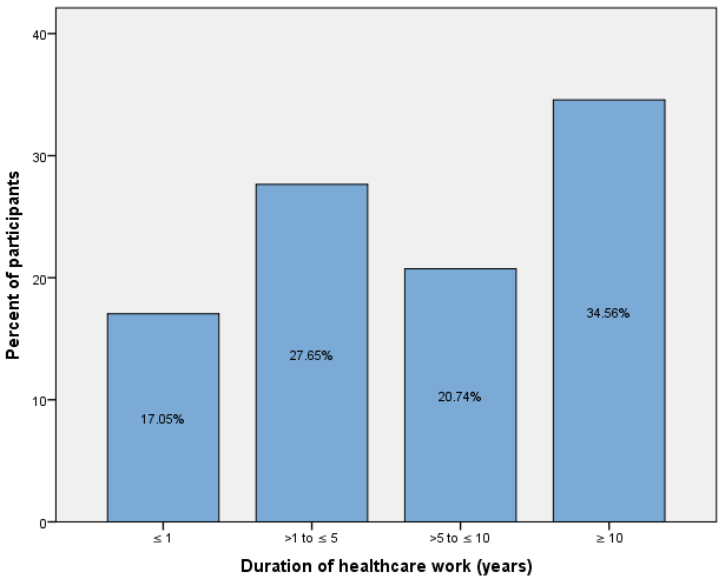

Figure 8.1 : Length of participants' experience in healthcare

The relationship between the duration of work in healthcare and the age of the participants was analysed using Spearman Rank Order correlation coefficient (nonparametric rank correlation). There was a strong positive correlation between the duration of work and the age of the healthcare workers (r = 0.83, n = 216, p < 001). These two variables were also plotted in a scatter plot (Figure 8.2).

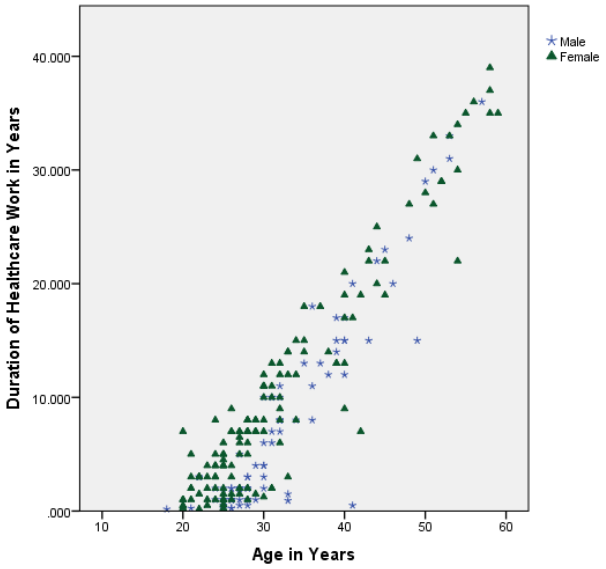

Figure 8.2: Scatter plot of participants' age and duration of healthcare work

8.1.6 Employment status

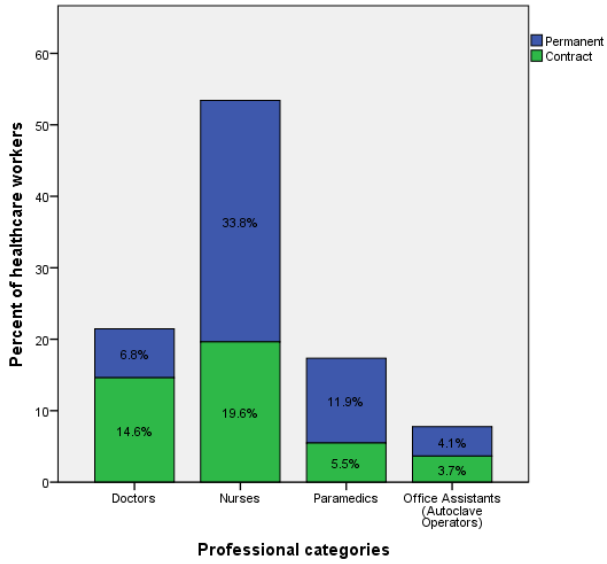

Figure 8.3: Percentages of healthcare workers in different professional categories

Of the total healthcare workers participating in the survey, about 57.0% (n = 124) were permanent staff, whereas 43.3% (n = 95) were temporary (contract based) staff. Figure 8.3 shows the percentage of permanent and temporary staff in different professional categories. The proportion of permanent staff was higher within each category except in the case of doctors. Of the total number of doctors participating in the survey, 68.1% (n = 32) were temporary staff.

8.2 Knowledge of Sterilization and Reuse of Medical Devices

8.2.1 Training

Based on this survey, of the healthcare workers working in primary and secondary care hospitals in Nepal, 51.6% (95% CI 42.0% - 61.0%) reported prior training in infection control/prevention (Table 8.5). Similarly, 36.1% (95% CI 28.4% - 44.5%) of the healthcare workers reported prior training in sterilization and disinfection. The proportion of healthcare workers reporting prior training on the operation of autoclaves was only 28% (95% CI 21.0% - 36.3%). Only 21.1% (95% CI 13.9% - 30.7%) of the healthcare workers reported prior training in all three areas.

Table 8.5: Proportion of healthcare workers reporting prior training

Training	Estimate	Standard Error	95% Confidence Interval	
			Lower	Upper
Infection Control/Prevention	51.6%	4.3%	42.0%	61.0%
Sterilization and Disinfection	36.1%	3.7%	28.4%	44.5%
Operation of Autoclaves	28.0%	3.5%	21.0%	36.3%

8.2.2 Practice of autoclave operation

Of the healthcare workers, 42.3% (95% CI 32.2% - 53.0%) reported operating autoclaves at some time by themselves. The proportions of healthcare workers reporting shelf-operation of

autoclaves in the three different hospital types are presented in Table 8.6. The difference in proportions across the three hospital types was not statistically significant (p = 0.83).

Table 8.6: Proportions of healthcare workers reporting self-operation of autoclaves across hospital types

Hospital type	Estimate	Standard Error	95% Confidence Interval	
			Lower	Upper
Zonal hospitals	39.0%	1.1%	36.6%	41.4%
District hospitals	42.8%	6.5%	29.3%	57.3%
District-level hospitals	45.5%	16.2%	16.2%	78.2%

Among the professional categories, nurses had the highest proportion who reported self-operation of autoclaves, at 50.1% (95% CI 33.1% - 67.1%; Table 8.7). There was a statistically significant association between profession and reported autoclave operation (p = 0.003); office assistants were not included as only those office assistants who were also autoclave operators were included in the survey.

Table 8.7: Proportions of healthcare workers reporting self-operation of autoclaves across professional categories

Professional Categories	Estimate	Standard Error	95% Confidence Interval	
			Lower	Upper
Doctors	7.8%	4.6%	2.0%	26.0%
Nurses	50.1%	7.9%	33.1%	67.1%
Paramedics	35.9%	6.7%	22.7%	51.7%

8.2.3 Responses to knowledge questions in rating scale formats

Figure 8.4 summarizes the responses of healthcare workers to five knowledge questions in rating scale formats. Questions K3 and K4 were negatively worded in the original questionnaire (Section 4.2.2) distributed to the healthcare workers i.e. a response of 7 (strongly agree) in the rating scales indicated incorrect responses to these questions. For clearer analysis and interpretation, responses to these questions were recoded to the reverse order so that all responses of 7 (strongly agree) indicated correct responses. As can be seen in

Figure 8.4, the majority of the responses to these knowledge questions were towards the correct (strongly agree) side. Of the healthcare workers, 86.8% (95% CI 79.9% - 91.7%) strongly agreed that used medical devices harbour a variety of microorganisms that could be transmitted among patients and healthcare workers. Likewise, 79.6% (95% CI 72.0% - 85.6%) of the healthcare workers strongly agreed that sterilization kills all microorganisms including spores. However, fewer than half (46.6%; 95% CI 39.5% - 53.8%) of the healthcare workers strongly agreed that immersion of medical devices in 2 % glutaraldehyde for 10 minutes does not constitute sterilization. Of the healthcare workers, 73.5% (95% CI 68.3% - 78.1%) strongly agreed that autoclaving is more effective than chemical methods for killing microorganisms. The percentage of healthcare workers strongly agreeing that wet sterilized packs of medical devices obtained from autoclaving are considered to be contaminated was only 37.6% (95% CI 29.0% - 46.6%).

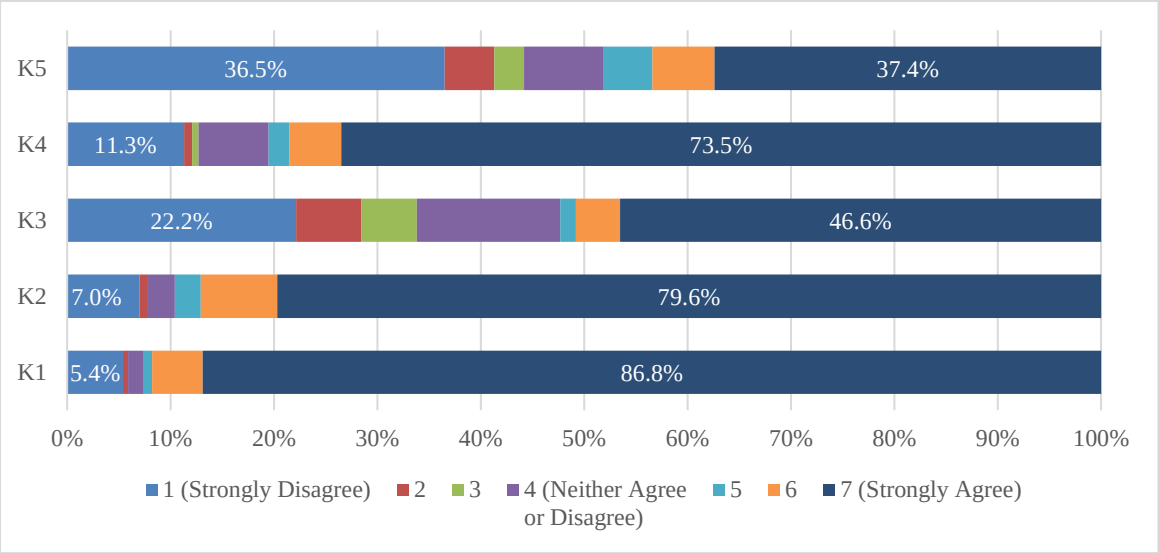

Figure 8.4: Healthcare workers' responses to five knowledge questions (K1–K5)

K1: Used medical devices harbour a variety of microorganisms that could be transmitted among patients and healthcare workers.

K2: Sterilization kills all microorganisms including spores.

K3: Immersion of medical devices in 2 % glutaraldehyde for 10 minutes does not constitute sterilization.

K4: Autoclaving is more effective than chemical methods for killing microorganisms.

K5: Wet sterilized packs of medical devices obtained from autoclaving are considered to be contaminated.

Ordinal Regression Models for complex samples were used to analyse the association of these responses with different characteristics of healthcare workers including duration of healthcare work, type of healthcare profession, infection control training, healthcare employment status (permanent or contract) and practice of autoclave operation (Table 8.8). Ordinal regression models showed that reported practice of self-operation of autoclave was not significantly associated with responses to any of the knowledge questions above. Remaining variables were found to be significantly associated with responses to one or more knowledge questions.

Compared to nurses, paramedics were less likely to know that used medical devices harbour a variety of microorganisms that could be transmitted among patients and healthcare workers (Model 1 in Table 8.8; OR = 0.35; 95% CI 0.16 - 0.77). On the other hand, permanent staff were more likely to have this knowledge than temporary staff (OR = 1.78; 95% CI 1.01 - 3.15).

Healthcare staff having infection control training were more likely to know that sterilization kills all microorganisms including spores (Model 2 in Table 8.8; OR = 2.12; 95% CI 1.02 - 4.42).

Doctors (OR = 0.20; 95% CI = 0.12 - 0.34), paramedics (OR = 0.24; 95% CI 0.12 - 0.50) and office assistants (OR = 0.12; 95% CI 0.03 - 0.45) were less likely to know that immersion of medical devices in 2 % glutaraldehyde for 10 minutes does not constitute sterilization compared to nurses (Model 3 in Table 8.8). On the other hand, permanent staff were more likely to have this knowledge than temporary staff (OR = 2.02; 95% CI 1.23 - 3.31).

Staff with longer experience in healthcare were less likely to know that autoclaving is more effective than chemical methods in killing microorganisms (Model 4 in Table 8.8; OR = 0.93; 95% CI 0.90 - 0.97). Similarly, paramedics (OR = 0.34; 95% CI 0.12 - 0.97) and office assistants (OR = 0.32; 95% CI 0.17 - 0.58) were also less likely to have this knowledge compared to nurses. However, staff with infection control training were more likely to have this knowledge (OR = 2.64; 95% CI 1.19 - 5.86). Permanent staff were also more likely to have this knowledge compared to temporary staff (OR = 2.42; 95% CI 1.30 - 4.50).

Table 8.8: Complex Samples - Ordinal Regression Models for responses of healthcare workers to knowledge questions in rating-scale formats

Predictor variable	Odds Ratio	95% Confidence Interval	P value***
Model 1: *Used medical devices harbour a variety of microorganisms that could be transmitted among patients and healthcare workers*			
Duration of healthcare work*	1.06	0.99 to 1.12	0.07
Healthcare profession			
Doctors	0.78	0.20 to 2.94	0.68
Paramedics	0.35	0.16 to 0.77	**0.01**
Office Assistants	1.76	0.24 to 12.56	0.54
Nurses**	1.00		
Infection control training	0.76	0.45 to 1.29	0.28
Healthcare employment status			
Permanent	1.78	1.01 to 3.15	< **0.05**
Temporary (contract)**	1.00		
Practice of autoclave operation	1.09	0.44 to 2.68	0.83
Model 2: *Sterilization kills all microorganisms including spores*			
Duration of healthcare work*	1.02	0.99 to 1.04	0.08
Healthcare profession			
Doctors	0.68	0.29 to 1.56	0.33
Paramedics	0.29	0.07 to 1.15	0.07
Office Assistants	1.44	0.23 to 8.83	0.66
Nurses**	1.00		
Infection control training	2.12	1.02 to 4.42	< **0.05**
Healthcare employment status			
Permanent	1.04	0.53 to 2.02	0.90
Temporary (contract)**	1.00		
Practice of autoclave operation	0.83	0.41 to 1.67	0.57

** Continuous variable, ** Reference category, *** Statistically significant results are shown in bold*

Table 8.8 continues to next page

Table 8.8 continues from previous page

Predictor Variable	Odds Ratio	95% Confidence Interval	P value***
Model 3: *Immersion of medical devices in 2 % glutaraldehyde for 10 minutes does not constitute sterilization.*			
Duration of healthcare work*	0.97	0.93 to 1.00	> 0.05
Healthcare profession			
Doctors	0.20	0.12 to 0.34	< **0.01**
Paramedics	0.25	0.12 to 0.50	< **0.01**
Office Assistants	0.12	0.03 to 0.45	**0.01**
Nurses**	1.00		
Infection control training	1.64	0.96 to 2.79	0.07
Healthcare employment status			
Permanent	2.02	1.23 to 3.31	**0.01**
Temporary (contract)**	1.00		
Practice of autoclave operation	0.64	0.39 to 1.02	0.06
Model 4: *Autoclaving is more effective than chemical methods for killing microorganisms.*			
Duration of healthcare work*	0.93	0.89 to 0.97	< **0.01**
Healthcare profession			
Doctors	0.52	0.20 to 1.36	0.16
Paramedics	0.34	0.12 to 0.96	**0.04**
Office Assistants	0.32	0.17 to 0.58	< **0.01**
Nurses**	1.00		
Infection control training	2.64	1.19 to 5.86	**0.02**
Healthcare employment status			
Permanent	2.42	1.30 to 4.50	**0.01**
Temporary (contract)**	1.00		
Practice of autoclave operation	0.64	0.27 to 1.51	0.28

** Continuous variable, ** Reference category, *** Statistically significant results are shown in bold*

Table 8.8 continues to next page

Table 8.8 continues from previous page

Predictor Variable	Odds Ratio	95% Confidence Interval	P value***
Model 5: *Wet sterilized packs of medical devices obtained from autoclaving are considered to be contaminated.*			
Duration of healthcare work*	1.03	1.01 to 1.05	**0.01**
Healthcare profession			
Doctors	0.41	0.14 to 1.17	0.09
Paramedics	0.33	0.17 to 0.65	< **0.01**
Office Assistants	1.50	0.49 to 4.58	0.43
Nurses**	1.00		
Infection control training	1.37	0.71 to 2.61	0.31
Healthcare employment status			
Permanent	0.64	0.30 to 1.36	0.22
Temporary (contract)**	1.00		
Practice of autoclave operation	1.25	0.63 to 2.50	0.48

** Continuous variable, ** Reference category, *** Statistically significant results are shown in bold*

Staff with longer experience in healthcare were more likely to know that wet sterilized packs of medical devices obtained from the autoclave are considered to be contaminated (Model 5 in Table 8.8; OR = 1.03; 95% CI 1.01 to 1.05). However, paramedics were less likely to have this knowledge compared to nurses (OR = 0.33; 95% CI 0.17 to 0.65).

8.2.4 Temperature and time for autoclaving

Of the healthcare workers, 80% (95% CI 75.4% - 84.0%) specified 121°C as the recommended temperature inside an autoclave for the autoclaves being used at their hospitals (Table 8.9). On the other hand, 5.7% (95% CI 3.6% - 8.9%) of the healthcare workers wrote *'Don't know'* in the space provided for writing a specific temperature. A significant association was found between hospital types and responses of healthcare workers about recommended sterilization temperature ($p = 0.01$). About 55% (95% CI 43.8% - 64.9%) of the healthcare workers reported 30 minutes as the effective holding/exposure period for sterilizing wrapped medical devices (Table 8.9). There was no statistically significant correlation between stated sterilization temperature and holding period ($r = 0.03$, $p = 0.56$).

Table 8.9: Temperature and holding period of autoclave cycles as stated by the respondents

	Estimate	Standard Error	95% Confidence Interval	
	Percentage		Lower	Upper
Temperature (°C)				
121	80.0%	1.9%	75.4%	84.0%
<121	11.9%	2.2%	7.9%	17.7%
>121	2.4%	1.0%	0.9%	6.2%
Don't know	5.7%	1.2%	3.6%	8.9%
Holding period (mins)				
30	54.6%	4.8%	43.8%	64.9%
<30	40.5%	4.5%	31.1%	50.7%
>30	4.9%	1.8%	2.1%	11.0%

A Logistic Regression Model for complex samples was used to analyse the association of knowledge of recommended temperature with various factors including duration of healthcare work, type of healthcare profession, infection control training, healthcare employment status (permanent or contract) and practice of autoclave operation (Table 8.10). Infection control training and healthcare profession were associated with the knowledge of sterilization temperature among healthcare workers. Paramedics and office assistants were less likely to identify the correct recommended temperature than nurses.

Table 8.10: Complex Samples - Logistic Regression model for knowledge of recommended temperature

Predictor Variable	Odds Ratio	95% Confidence Interval	P value***
Model: *For autoclaves being used in this hospital, the temperature inside the autoclave chamber while sterilizing medical devices is 121°C.*			
Duration of healthcare work*	1.00	0.93 to 1.07	0.97
Healthcare profession			
Doctors	0.51	0.19 to 1.32	0.15
Paramedics	0.25	0.09 to 0.66	**0.01**
Office Assistants	0.03	0.00 to 0.18	< **0.01**
Nurses**	1.00		
Infection control training	3.16	1.62 to 6.20	< **0.01**
Healthcare employment status			
Permanent	1.54	0.50 to 4.78	0.42
Temporary (contract)**	1.00		
Practice of autoclave operation	0.63	0.17 to 2.23	0.43

** Continuous variable, ** Reference category, *** Statistically significant results are shown in bold*

8.2.5 Shelf life

Of the healthcare workers, 78.8% (95% CI 69.4% - 85.9%) thought that sterilized wrapped medical devices can be stored for 7 days at room temperature before using them (Table 8.11). Only 3.4% (95% CI 0.7% - 15.2%) of the healthcare workers thought that sterilized wrapped medical devices could be stored for more than 7 days before use. Healthcare workers' opinion about the shelf life was not significantly associated with hospital type (Adjusted F = 0.60, p = 0.55).

Table 8.11: Healthcare workers' opinion on shelf life of sterilized medical devices

Shelf life	Estimate	Standard Error	95% Confidence Interval	
			Lower	Upper
7 Days	78.8%	3.7%	69.4%	85.9%
< 7 Days	17.8%	2.9%	12.2%	25.2%
> 7 Days	3.4%	2.4%	0.7%	15.2%

8.2.6 Decontamination of specific medical devices

Healthcare workers were asked to identify the single highest level of decontamination process appropriate for some specific medical devices including auroscope ear piece, ear syringe, metal forceps, scalpel handle, thermometer and vaginal speculum. Table 8.12 provides percentages of healthcare workers considering a process (cleaning, disinfection or sterilization) as the highest level of decontamination appropriate for the reuse of these medical devices.

Table 8.12: Participants' opinion on the highest level of decontamination appropriate for reusable medical devices

Medical device		Appropriate highest level decontamination process		
		Cleaning	**Disinfection**	**Sterilization**
Auroscope ear piece	Estimate	39.3%	**41.1%***	19.6%
	95% CI	29.7% - 49.8%	32.5% - 50.3%	15.0% - 25.2%
	SE	4.6%	4.0%	2.3%
Ear syringe	Estimate	26.7%	43.9%	**29.4%***
	95% CI	18.4% - 36.9%	35.0% - 53.3%	21.0% - 39.6%
	SE	4.2%	4.2%	4.2%
Metal forceps	Estimate	1.2%	7.5%	**91.3%***
	95% CI	0.5% - 2.8%	4.4% - 12.6%	85.2% - 95.0%
	SE	0.5%	1.8%	2.1%
Scalpel handle	Estimate	5.2%	10.1%	**84.7%***
	95% CI	2.1% - 12.2%	5.8% - 17.0%	79.4% - 88.9%
	SE	2.1%	2.5%	2.1%
Thermometer	Estimate	66.8%	**32.7%***	0.5%
	95% CI	56.5% - 75.8%	23.7% - 43.1%	0.1% - 3.8%
	SE	4.4%	4.4%	0.5%
Vaginal speculum	Estimate	0.9%	11.3%	**87.9%***
	95% CI	0.2% - 3.9%	5.7% - 21.2%	78.6% - 93.5%
	SE	0.6%	3.4%	3.2%

** Recommended decontamination process*

8.2.7 Sterilization of medical devices for neurosurgical procedures

Of the healthcare workers, 45.2% (95% CI 36.2% - 50.3%) thought that the routine sterilization process for medical devices needed to be changed for neurosurgical procedures. Indeed, 6.8% (95% CI 3.7% - 12.0%) of the healthcare workers wrote *'Don't know'* leaving the yes/no options unchecked. There was no significant association between the response about sterilization of medical devices for neurosurgical procedures and the hospital type (Adjusted F = 3.11, p = 0.54).

An open ended question was also asked of healthcare workers to find out why they thought that a change in the routine sterilization process is required for medical devices used for neurosurgical procedures. Most of the healthcare workers thought a change is required because of the risk (in terms of the possibility of acquiring an infection during the procedure) or complexity of neurosurgical procedures. Only one healthcare worker mentioned prions and their resistance to sterilization processes as the following:

> "Sterilization process is useful for the neurosurgical instrument. There is a chance of infection of CJD disease transmission, so, if possible the routine sterilization is needed. Prion disease is resistant to the heat and chemical method of sterilization, so, the instrument is needed to be routinely sterilized. But in normal or general setting, there is the issue of CJD disease of low incidence, in that case the instrument is not regularly or routinely sterilized."

8.2.8 Patients' concern

Of the healthcare workers, 43.1% (95% CI 36.2% - 50.3%) stated that patients visiting their hospital sometimes show concern about the sterility of medical devices. A significant association was found between this opinion and hospital types (Adjusted F = 16.20, p < 0.01). The higher level hospitals had a lower percentage of healthcare staff stating that patients show concern about the sterility of medical devices.

8.2.9 Recommendations for improvement

Key areas where healthcare workers mentioned improvement needs were training and education, routine practices, monitoring and supervision, management, human resources, infrastructure and alternative methods. Training of staff was the most common recommendation made by the healthcare workers for improvement of sterilization and reuse of medical devices in their hospitals. A list of common recommendations made by the healthcare workers for the improvement of medical device reprocessing in their hospitals is given in Appendix 26.

8.2.10 Sterilization during emergencies

Healthcare workers were asked (an open ended question) about interim methods used for sterilization when an existing autoclave in their hospital malfunctions or breaks. Answers from the healthcare workers ranged from using some other physical or chemical methods of sterilization to stopping surgical procedures. Of the physical methods, boiling was the most frequently reported interim method. Flaming, sun drying, steaming, and sterilization using a hot air oven were less frequently reported physical methods. “Chemical method” was the second most common term used by the healthcare workers while reporting interim methods. Chemical sterilization using glutaraldehyde solution was commonly reported as an interim method of sterilization. Other reported chemical methods included the use of hypochlorite solution, betadine and spirit. Similarly, high level disinfection using chemical or physical methods was also reported by some healthcare workers.

In addition to the use of alternative chemical or physical methods of sterilization, healthcare workers also reported other interim options until a malfunctioning autoclave is repaired. Such options included cancellation of surgical procedures, referring patients to other hospitals, continuing sterilization with the same (malfunctioning) autoclave and using broad spectrum antibiotics for patients to reduce the infection risk associated with medical devices. One of the doctors wrote about the use of antibiotics when the autoclave is not working as the following:

"Till then we will use disinfection technique for a minor procedure, follow strict aseptic technique with broad spectrum antibiotics. But, for a major procedure, we can't take the risk. So, will be referred to the higher centre."

8.3 Attitudes towards Sterilization and Reuse of Medical Devices

Figure 8.5 summarizes the responses of healthcare workers to twelve attitude questions in rating scale formats. Statements A3, A5, A7, A8, A10 and A12 were negatively worded in the original questionnaire distributed to the healthcare workers i.e. a response of 7 (strongly agree) in the rating scales for the statements indicated a strong negative attitude. However, for clearer analysis and interpretation (and consistency with reporting the responses to other questions), responses to these questions were recoded to reverse order so that all responses of 7 (strongly agree) indicated a strong positive attitude. As can be seen in Figure 8.5, the majority of the responses to the attitude questions were towards the positive (strongly agree) side. However, for questions A10 and A12, only 16.10% (95% CI 11.1% - 22.7%) and 30.10% (95% CI 23.2% - 38.1%) respectively strongly agreed with the statements.

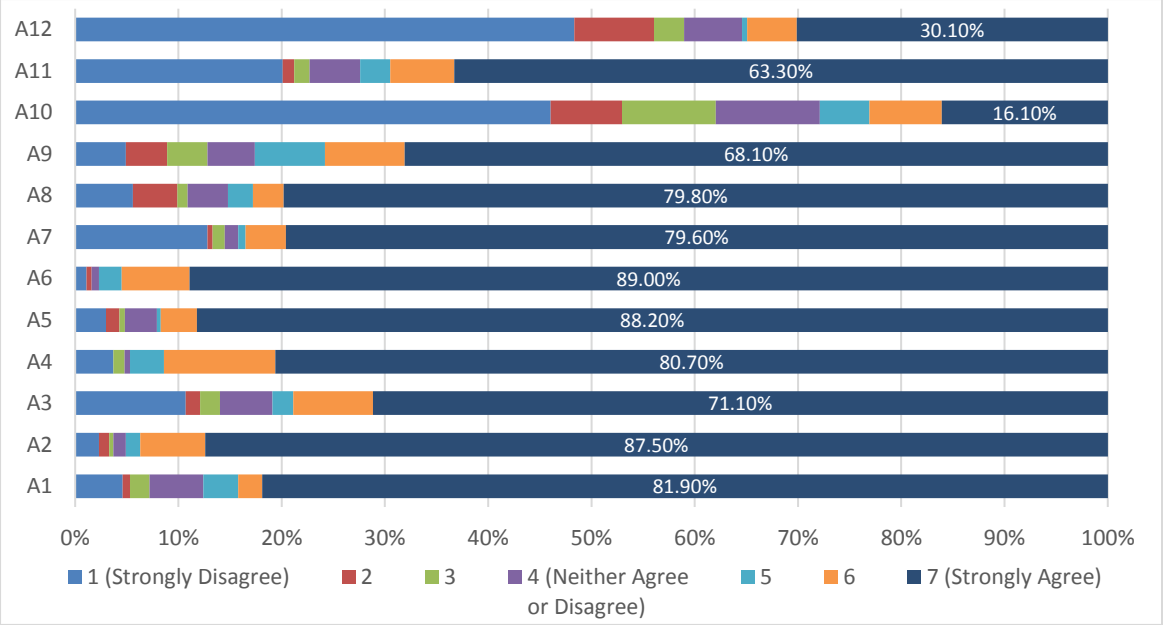

Figure 8.5: Healthcare workers' responses to twelve attitude questions (A1-A12)

A1: Reuse of medical devices is an important patient safety issue.

A2: Decontamination of medical devices reduces the risk of infection in patients and healthcare workers.

A3: Written policies and standards are necessary for ensuring appropriate decontamination of medical devices.

A4: Availability of sterilizers and supplies supports routine decontamination of medical devices.

A5: Monitoring of the sterilization process deserves the same attention to detail applied to other key patient care activities.

A6: Training on the operation of sterilizer/autoclave helps ensure adequate sterilization of medical devices.

A7: Cleaning before sterilization is a necessary process.

A8: If an instrument is not soiled visibly, we still need to clean it before sterilization.

A9: I would feel safe being treated as a patient using medical devices sterilized in this hospital.

A10: The number of staff involved in decontamination of medical devices in this hospital is adequate.

A11: Every patient attending healthcare facilities must be considered potentially HIV positive.

A12: Deviation from routine reprocessing procedures for medical devices is not required when the devices had been used in patients with HIV.

8.3.1 Patient safety

Of the healthcare workers, 81.9% (95% CI 76.8% - 86.1%) strongly agreed that reuse of medical devices is an important patient safety issue (Figure 8.5). Ordinal Regression Model for complex samples was used to analyse the association of this response with different variables including duration of work in healthcare, healthcare profession, infection control training, current employment status and practice of autoclave operation. None of these variables were significantly associated with the response.

8.3.2 Decontamination of medical devices

Of the healthcare workers, 87.5 % (95% CI 81.0% - 92.0%) strongly agreed that decontamination of medical devices reduces the risk of infection in patients and healthcare workers. However, this response was not significantly associated with duration of work in healthcare, healthcare profession, infection control training, current employment status or practice of autoclave operation.

8.3.3 Policies and standards

Of the healthcare workers, 71.1% (95% CI 64.0% - 77.2%) strongly agreed that written policies and standards are necessary for ensuring appropriate decontamination of medical devices. The Ordinal Regression Model for complex samples (Table 8.13) showed that office assistants were less likely to have a positive attitude towards policies and standards compared to nurses (OR = 0.35; 95% CI 0.15 - 0.83).

8.3.4 Availability of sterilizers and supplies

Of the healthcare workers, 80.7% (95% CI 73.2% - 86.4%) strongly agreed that availability of sterilizers and supplies supports routine decontamination of medical devices. No significant association was found between this agreement and the variables stated above (see Table 8.13 for the variables).

Table 8.13: Complex Samples - Ordinal Regression Model for attitude of healthcare workers towards policies and standards

Predictor Variable	Odds Ratio	95% Confidence Interval	P value***
Model: *Written policies and standards are necessary for ensuring appropriate decontamination of medical devices.*			
Duration of healthcare work*	1.0	0.93 to 1.01	0.09
Healthcare profession			
Doctors	0.5	0.21 to 1.06	0.07
Paramedics	0.6	0.24 to 1.49	0.24
Office Assistants	0.3	0.15 to 0.83	**0.02**
Nurses**	1.0		
Infection control training	1.2	0.46 to 2.92	0.73
Healthcare employment status			
Permanent	1.1	0.54 to 2.18	0.80
Temporary (contract)**	1.0		
Practice of autoclave operation	0.8	0.43 to 1.57	0.52

** Continuous variable, ** Reference category, *** Statistically significant results are shown in bold*

8.3.5 Monitoring

Of the healthcare workers, 88.2% (95% CI 84.6% - 91.1%) strongly agreed that monitoring of the sterilization process deserves the same attention to detail applied to other key patient care activities. This attitude was not significantly associated with duration of work in healthcare, healthcare profession, infection control training, current employment status and practice of autoclave operation.

8.3.6 Training

Of the healthcare workers, 89.0% (95% CI 84.9% - 92.0%) strongly agreed that training on the operation of sterilizer/autoclave helps ensure adequate sterilization of medical devices. The Ordinal Regression Model for complex samples showed that this attitude towards training was less likely to be possessed by doctors (OR = 0.32; 95% CI 0.13 - 0.82) compared

to nurses (Table 8.14). On the other hand, healthcare workers who reported prior infection control/prevention training were less likely to have a positive attitude towards training (OR = 0.31; 95% CI 0.15 - 0.73).

Table 8.14: Complex Samples - Ordinal Regression Model for attitude of healthcare workers towards training

Predictor Variable	Odds Ratio	95% Confidence Interval	P value***
Model: Training on the operation of sterilizer/autoclave helps ensure adequate sterilization of medical devices			
Duration of healthcare work*	1.05	1.00 to 1.10	0.05
Healthcare profession			
Doctors	0.32	0.13 to 0.82	**0.02**
Paramedics	0.82	0.13 to 5.03	0.81
Office Assistants[1]	1.34	1.00 to 18.46	0.81
Nurses**	1.00		
Infection control training	0.31	0.15 to 0.73	**0.01**
Healthcare employment status			
Permanent	0.37	0.12 to 1.16	0.08
Temporary (contract)**	1.00		
Practice of autoclave operation	1.251	0.46 to 3.38	0.626

** Continuous variable, ** Reference category, *** Statistically significant results are shown in bold*

[1] all of the office assistants strongly agreed with this statement (i.e. marked on 7 on the rating scale) but the response of one of the office assistant was assumed to be 6 instead of 7 to make this regression analysis possible.

8.3.7 Cleaning of medical devices

Of the healthcare workers, 79.6% (95% CI 74.2% - 84.1%) strongly agreed that cleaning before sterilization is a necessary process. This attitude towards cleaning of medical devices was not significantly associated with duration of work in healthcare, healthcare profession, infection control training, current employment status and practice of autoclave operation. Similarly, of the healthcare workers, 79.8% (95% CI 72.3% - 85.7%) strongly agreed that we

need to clean medical devices before sterilization even if they are not soiled visibly. Paramedics were less likely to agree with this statement compared to nurses (Table 8.15; OR = 0.24; 95% CI 0.06 - 0.89). On the other hand, permanent staff were more likely to agree with this statement than temporary staff (OR = 1.40; 95% CI 1.06 - 1.84).

Table 8.15: Complex Samples - Ordinal Regression Models for attitude of healthcare workers towards cleaning of medical devices

Predictor Variable	Odds Ratio	95% Confidence Interval	P value***
Model : If an instrument is not soiled visibly, we still need to clean it before sterilization			
Duration of healthcare work*	0.98	0.92 to 1.05	0.53
Healthcare profession			
Doctors	0.42	0.12 to 1.42	0.14
Paramedics	0.24	0.06 to 0.89	**0.04**
Office Assistants	0.49	0.14 to 1.68	0.23
Nurses**	1.00		
Infection control training	1.02	0.41 to 2.52	0.96
Healthcare employment status			
Permanent	1.40	1.06 to 1.84	**0.02**
Temporary (contract)**	1.00		
Practice of autoclave operation	1.00	0.45 to 2.23	1.00

** Continuous variable, ** Reference category, *** Statistically significant results are shown in bold*

8.3.8 Attitude towards being treated as a patient in the hospital

Of the healthcare workers, 68.1% (95% CI 56.0% - 78.2%) strongly agreed that they would feel safe being treated as a patient using medical devices sterilized in their hospitals. Doctors were less likely to feel safe being treated as a patient compared to nurses (Table 8.16; OR = 0.23; 95% CI 0.06 - 0.87).

Table 8.16: Complex Samples - Ordinal Regression Model for attitude of healthcare workers towards being treated as a patient

Predictor Variable	Odds Ratio	95% Confidence Interval	P value***
Model: I would feel safe being treated as a patient using medical devices sterilized in this hospital			
Duration of healthcare work*	0.99	0.96 to 1.03	0.68
Healthcare profession			
Doctors	0.23	0.06 to 0.87	**0.03**
Paramedics	1.32	0.23 to 7.76	0.73
Office Assistants	2.84	0.34 to 23.36	0.30
Nurses**	1.00		
Infection control training	1.49	0.68 to 3.26	0.28
Healthcare employment status			
Permanent	0.95	0.40 to 2.27	0.90
Temporary (contract)**	1.00		
Practice of autoclave operation	1.11	0.26 to 4.72	0.88

** Continuous variable, ** Reference category, *** Statistically significant results are shown in bold*

8.3.9 Staffing

Only 16.1% (95% CI 11.1% - 22.7%) of healthcare staff strongly agreed that the number of staff involved in decontamination of medical devices in their hospital was adequate. Duration of work in healthcare, healthcare profession, infection control training, current employment status and practice of autoclave operation were not significantly associated with the attitude of healthcare workers towards staffing.

8.3.10 HIV infection

Of the healthcare workers, 63.3% (95% CI 56.4% - 69.8%) strongly agreed that every patient attending healthcare facilities must be considered potentially HIV positive. Healthcare workers who reported prior infection control training were more likely to agree with this opinion (Model 1 in Table 17; OR = 2.576; 95% CI 1.288 – 5.152; p = 0.012). On the other

hand, paramedics were less likely to agree with this opinion compared to nurses (Model 1 in Table 8.17; OR = 0.37; 95% CI 0.16 - 0.84).

Of the healthcare workers, 30.1% (95% CI 23.2% - 38.1%) strongly agreed that deviation from routine reprocessing procedures for medical devices is not required when the devices had been used in patients with HIV. Permanent staff were more likely to agree with this opinion compared to temporary staff (Model 2 in Table 8.17; OR = 3.11; 95% CI 2.13 - 4.56). Healthcare workers' agreement with this opinion was not statistically significantly associated with their response about considering all patients potentially HIV-positive.

Table 8.17: Complex Samples - Ordinal Regression Models for attitude of healthcare workers towards HIV and reprocessing of medical devices

Predictor Variable	Odds Ratio	95% Confidence Interval	P value***
Model 1: Every patient attending healthcare facilities must be considered potentially HIV positive			
Duration of healthcare work*	1.00	0.96 to 1.04	0.93
Healthcare profession			
Doctors	0.68	0.31 to 1.48	0.29
Paramedics	0.37	0.16 to 0.84	**0.02**
Office Assistants	0.43	0.11 to 1.72	0.21
Nurses**	1.00		
Infection control training	2.58	1.29 to 5.15	**0.01**
Healthcare employment status			
Permanent	1.35	0.74 to 2.46	0.29
Temporary (contract)**	1.00		
Practice of autoclave operation	0.52	0.24 to 1.12	0.09
Model 2: Deviation from routine reprocessing procedures for medical devices is not required when the devices had been used in patients with HIV			
Duration of healthcare work*	0.95	0.93 to 0.98	< **0.01**
Healthcare profession			
Doctors	0.74	0.35 to 1.57	0.39
Paramedics	1.02	0.42 to 2.46	0.96
Office Assistants	0.71	0.30 to 1.71	0.41
Nurses**	1.00		
Infection control training	1.48	0.83 to 2.63	0.16
Healthcare employment status			
Permanent	3.12	2.13 to 4.56	< **0.01**
Temporary (contract)**	1.00		
Practice of autoclave operation	1.55	0.73 to 3.29	0.23

** Continuous variable, ** Reference category, *** Statistically significant results are shown in bold*

8.4 Discussion

8.4.1 Survey response proportion

A high response proportion (93.6%) in this survey could have been because of the mode of administration of the questionnaire. The questionnaires were distributed to healthcare workers in person and they were also followed up for completion and return of the questionnaire. In a similar survey conducted by Paudyal *et al.* (2008) in five hospitals (2 public and 3 private) in Kathmandu, Nepal, assessing knowledge, attitudes and practices of doctors and nurses in the area of infection control, the response rate was 80%. Therefore, the response rate obtained in this survey is not unusual. However, the response rates in postal surveys conducted in the UK and Northern Ireland were considerably lower (53.1%, 53% and 30%) than in this study (Coulter *et al.*, 2001; McNally *et al.*, 2001; Smyth *et al.*, 1999). On the other hand, in Ethiopia, a response rate of 97.8% was obtained in a structured interview survey assessing knowledge, attitudes and practices of health care workers on infection prevention (Gulilat & Tiruneh, 2014). These findings indicate that structured interviews or surveys administering questionnaires in person can yield a higher response proportion compared to postal surveys. These methods could be more useful in settings where postal services are not very reliable. Although these methods are expected to result in higher response proportions, they are more expensive than postal surveys.

8.4.2 Knowledge

8.4.2.1 Training

More than 50% of the healthcare staff reported prior training on infection prevention and control. Comparatively smaller percentages of healthcare workers reported more specific training in areas such as sterilization and disinfection (36.1%) and operation of autoclaves (28.0%). In a survey of primary care practices in the UK, 55% of practice nurses and general practitioners reported general training in cross-infection whereas 26% reported specific training in loading autoclaves (Coulter *et al.*, 2001). Though the findings from both Nepal and the UK were similar, it cannot be overlooked that the UK study was conducted many years earlier and the health systems of the two countries are quite different. Apparently, the

only training being conducted in the area of infection prevention and control for healthcare workers in Nepal is "Infection Prevention and Healthcare Waste Management Training" (NHTC - Ministry of Health and Population - Government of Nepal, 2015b). No formal training focussed particularly on sterilization and disinfection, and operation of autoclaves was found while reviewing government documents and relevant literature. It is possible that those who reported trainings on sterilization and disinfection, and/or operation of autoclaves in this study could have just considered these training as components of broader infection control/prevention training and reported them as well. This possibility is supported by the finding that 21.1% of the healthcare workers reported training in all three areas. The percentage of healthcare workers reporting that they had received training on disinfection and sterilization (i.e. a specific training course) was smaller than the percentage of healthcare workers reporting infection prevention/control training (i.e. a broader training course); likewise, the percentage of healthcare workers reporting training on autoclave operation (i.e. more specific training course) was smaller than the percentage of healthcare workers reporting training on disinfection and sterilization (see Table 8.5). The finding that only about half of the healthcare workers reported prior infection control/prevention training indicates the need for scaling up training and education of healthcare workers in this area.

8.4.2.2 Factors associated with healthcare workers' knowledge

More than 70% of healthcare workers had proper knowledge about specific aspects of the sterilization of medical devices. These aspects included microbial contamination of used medical devices, the definition of sterilization, the effectiveness of autoclaving, and the recommended temperature for steam sterilization. However, there were some aspects where a smaller percentage of healthcare workers had proper knowledge. Fewer than 50% of healthcare workers strongly agreed with knowledge statements about chemical (glutaraldehyde) sterilization and wet sterilized packages. Regression models (see Table 8.8 and Table 8.10) revealed that paramedics were less likely to give correct answers compared to nurses for all of these knowledge questions, except for the definition of sterilization. Similarly, compared to nurses, office assistants were less likely to give the correct answers for glutaraldehyde sterilization, the effectiveness of autoclaving, and the recommended steam sterilization temperature. On the other hand, doctors were also less likely to give correct response to the question about glutaraldehyde sterilization, compared to nurses. Though all

categories of healthcare staff need continued training and education, these findings show that paramedics and office assistants need comparatively more attention in order to improve their knowledge in the area of sterilization. Better knowledge among nurses could have been because of their greater involvement in routine infection control activities in hospitals.

Compared to temporary staff, permanent staff were more likely to give correct answers for many of the knowledge items, including microbial contamination of used medical devices, glutaraldehyde sterilization, and effectiveness of autoclaving. This could be because of relatively better opportunities for training and education given to permanent staff than to temporary staff. Here, it is important to recall that the proportion of temporary staff participating in this survey was substantial (43%, n = 95). The infection control training was positively associated with correct responses to some knowledge items including microbial contamination of reused medical devices, the effectiveness of autoclaving, and steam sterilization temperature. In addition, there was no statistically significant negative association between infection control training and responses to any of the knowledge questions. These findings support the importance of training for improving knowledge of healthcare workers in the sterilization of medical devices. More experienced healthcare workers were more likely to have correct knowledge about wet sterilized packs of medical devices. However, surprisingly, more experienced healthcare workers were less likely to have proper knowledge about the effectiveness of autoclaving, adjusted for healthcare profession, employment status, infection control training and practice of autoclave operation (see Table 8.8). The practice of autoclave operation was not statistically significantly associated with responses to any of the knowledge questions discussed above. The healthcare workers were asked whether they sometimes operated an autoclave. They were likely to answer ‘yes’ even if they had operated an autoclave only once. Therefore, the reported practice of autoclave operation could not have been statistically significantly associated with the responses to any of the knowledge questions.

8.4.2.3 Chemical sterilization using glutaraldehyde

Fewer than 50% of healthcare workers strongly agreed that immersion of medical devices in 2% glutaraldehyde for 10 minutes does not constitute sterilization. This chemical method is usually used for a high-level disinfection of medical devices that cannot resist high

temperatures. However, immersion of medical devices to 2% glutaraldehyde solution for a longer time period is commonly considered as sterilization. For example, the Reference Manual for Infection Prevention and Healthcare Waste Management considers immersion of medical devices in 2% glutaraldehyde solution for 10 hours as sterilization (NHTC - Ministry of Health and Population - Government of Nepal, 2015b). Some other international guidelines have also mentioned the sterilizing (sporicidal) activity of 2% glutaraldehyde when medical devices are exposed for a longer period of time (Rutala *et al.*, 2008; WHO, 2016a). The response of healthcare workers in this matter indicated some ambiguity as 22.2% of healthcare workers strongly agreed that immersion of medical devices in 2% glutaraldehyde for 10 minutes constituted sterilization and about 14% of them remained neutral. In three similar previous studies from the UK, 13%, 16% and 27% of healthcare workers thought that soaking in 2% glutaraldehyde for 10 minutes constituted sterilization (Allen *et al.*, 1997; McNally *et al.*, 2001; Smyth *et al.*, 1999). In light of these previous findings, the response of healthcare workers in Nepal was not surprising. However, there is a clear need for education for healthcare workers about proper use of glutaraldehyde in hospitals. There are health hazards, such as contact dermatitis, throat and lung irritation, associated with the use of glutaraldehyde in healthcare facilities. Healthcare workers need to be educated on such issues as well (Shaffer & Belsito, 2000; Takigawa & Endo, 2006).

8.4.2.4 Sterilization temperature and time

Appropriate temperature, time (holding period) and moisture are imperative to an adequate moist-heat sterilization cycle (Young, 1997). Of the healthcare workers in primary and secondary care hospitals, 80.0% identified 121°C as the recommended temperature for sterilization of medical devices in their hospitals. This is consistent with the temperature recommended in the national Reference Manual for Infection Prevention and Healthcare Waste Management (NHTC - Ministry of Health and Population - Government of Nepal, 2015b). It is extremely important to note that all of the office assistants (i.e. autoclave operators) wrote *'Don't know'* in the space provided for writing the required temperature for sterilizing medical devices. Healthcare workers were also asked to provide the time period required for sterilizing wrapped medical devices at the temperature reported by them. More than half (54.7%) of the healthcare workers (see Table 8.9) thought that medical devices should be kept for 30 minutes at the reported temperature. This is consistent with the holding

period recommended for sterilizing wrapped medical devices at 121°C by the national reference manual (NHTC - Ministry of Health and Population - Government of Nepal, 2015b). The proportion of healthcare workers reporting a holding period of 30 minutes (54.7%) was considerably lower than the proportion of healthcare workers reporting 121°C as the recommended temperature (80.0%), while 40.5% of the healthcare workers thought that the holding period required at the recommended temperature was less than 30 minutes. In principle, higher sterilization temperature requires shorter holding periods (Young, 1997). However, there was no significant correlation between the temperature and the holding period reported by the healthcare workers. This indicates a lack of knowledge among healthcare staff about the appropriate holding period for steam sterilization. Recommendations made in different international guidelines and standards about sterilization temperature and holding period are discussed in sections 2.4.1.1 and 6.7.4.

8.4.2.5 Shelf life of sterilized packages

About 79% of the healthcare workers thought that wrapped sterilized medical devices could be stored for seven days at room temperature before use. The Reference Manual for Infection Prevention and Healthcare Waste Management (NHTC - Ministry of Health and Population - Government of Nepal, 2015b) has recommended the same time period for storage of wrapped medical devices. However, the logic behind this recommendation is not clear. A shelf life of 7 days is very much less than the recommendations made by most other guidelines and studies. There seems to be growing support for event-related shelf life of sterilized medical devices rather than time-related shelf life (Barrett *et al.*, 2003; Bhumisirikul *et al.*, 2003; Webster *et al.*, 2003). When event-related shelf life is followed, wrapped medical devices are stored for a longer period of time, i.e. until some event such as tearing or damage to the wrapping leads to potential contamination of packages by microorganisms. Implementing a short shelf life for sterilized packages of medical devices demands additional resources for more frequent sterilization. In a resource limited country like Nepal, it could be more economical to use a longer shelf life for sterilized packages. At the same time, the importance of appropriate sterilization, packaging (material and method), storage, environmental conditions, and handling of the packages cannot be overlooked (Japp, 1997). There is no universal recommendation for the shelf life of sterilized packages. Lakhan *et al.* (2013) conducted a review of evidence about the shelf life of sterilized packaged items and pointed

out the necessity of a risk assessment before implementing event-related or time-related shelf life for sterilized packages. Packaging methods used and storage conditions in hospitals in Nepal are discussed in sections 7.5.6 and 7.5.8, and recommendations about the shelf life of medical devices in the context of Nepal are made in Section 9.5.

When discussing the shelf life of sterilized packages of medical devices, dryness of sterilized packages should not be forgotten. Guidelines advise that wet sterilized packages of medical devices should be considered contaminated because wet packages can easily facilitate the entrance and growth of microorganisms (Rutala *et al.*, 2008; WHO, 2016a). However, knowledge of healthcare workers in this matter was found to be quite divided, with 37.4% of the healthcare workers strongly agreeing with the statement about wet packaging while a similar percentage (36.5%) strongly disagreed. Newer healthcare workers and paramedics need more education about this than other healthcare workers (see Table 8.8).

8.4.2.6 Decontamination of specific medical devices

There was relatively superior knowledge among healthcare workers about appropriate decontamination of some medical devices, including metal forceps, scalpel handles and vaginal speculum (91.3%, 84.7% and 87.9% respectively) compared to some other medical devices such as auroscope ear pieces, ear syringes and thermometers (41.1%, 29.4% and 32.7% respectively). It is noteworthy that metal forceps and scalpel handles are usually used for invasive procedures, including surgical procedures. Few previous studies have assessed the knowledge of healthcare workers about appropriate decontamination of these medical devices. Results from this study and two previous studies have been compared in Table 8.18. The results of this study were comparable with the results from two previous studies conducted in the UK, though this study was conducted more than 15 years later. However, comparatively, higher percentages of healthcare workers in Nepal were unable to correctly identify appropriate decontamination processes for auroscope ear pieces and thermometers. In all three studies, fewer than 30% of healthcare workers correctly identified the appropriate decontamination process for ear syringes. These findings reveal lack of knowledge among many healthcare workers in Nepal about decontamination of some medical devices. Proper education and training in this area could improve the knowledge of these healthcare workers.

A list of medical devices being reused in each hospital, with specific guidance for reprocessing each of them, could prove useful for educating healthcare workers.

Table 8.18: Reported healthcare workers' opinion on the highest level of decontamination appropriate for reusable medical devices

Medical device	Studies	Appropriate highest level decontamination process		
		Cleaning	Disinfection	Sterilization
Auroscope ear piece	This study	39.3%	**41.1%***	19.6%
	McNally *et al.* (2001)[1]	6.7%	68.9%	24.4%
	Smyth *et al.* (1999)[2]	23.0%	72.0%	9.0%
Ear syringe	This study	26.7%	43.9%	**29.4%***
	McNally *et al.* (2001)[1]	9.1%	61.4%	22.7%
	Smyth *et al.* (1999)[2]	26.5%	64.3%	11.2%
Metal forceps	This study	1.2%	7.5%	**91.3%***
	McNally *et al.* (2001)[1]	0.0%	0.0%	100.0%
	Smyth *et al.* (1999)[2]	2.1%	6.2%	96.9%
Scalpel handle	This study	5.2%	10.1%	**84.7%***
	McNally *et al.* (2001)[1]	2.9%	5.9%	91.2%
	Smyth *et al.* (1999)[2]	6.5%	4.8%	90.3%
Thermometer	This study	66.8%	**32.7%***	0.5%
	McNally *et al.* (2001)[1]	15.2%	72.7%	12.1%
	Smyth *et al.* (1999)[2]	21.3%	77.7%	6.4%
Vaginal speculum	This study	0.9%	11.3%	**87.9%***
	McNally *et al.* (2001)[1]	2.2%	4.4%	93.3%
	Smyth *et al.* (1999)[2]	3.2%	5.4%	97.8%

** Recommended decontamination process*

[1] University health services in the UK, some respondents have provided more than one decontamination process for each item

[2] General practices in Northern Ireland, some respondents have provided more than one decontamination process for each item

8.4.2.7 Prions and sterilization of medical devices

Healthcare workers were asked whether it was necessary to change the routine sterilization process for medical devices for neurosurgical procedures. The purpose of including this question was to assess whether healthcare workers were aware of prion diseases (including CJD) and about the ineffectiveness of routine sterilization processes to denature prions (disscussed in Section 2.2.1). Of the healthcare workers, 45.2% thought that routine sterilization processes for medical devices needed to be changed for neurosurgical procedures. The healthcare workers were also asked why the routine sterilization process needed to be changed for neurosurgical procedures. Of the healthcare workers who thought the routine sterilization process needed to be changed, only one (doctor) mentioned prions and their resistance to chemical and physical methods of denaturation. However, that respondent did not say anything about the need for changing the routine sterilization processes for medical devices used for neurosurgical procedures. Most of the healthcare workers thought that a change in routine sterilization is needed because of the higher sensitivity or complexity of neurosurgical procedures. This indicated a lack of confidence among healthcare workers about the sterility of medical devices reprocessed in their hospitals. More importantly, almost all of the healthcare workers working in primary and secondary care hospitals did not know about prions and their resistance to routine sterilization processes. This finding needs to be understood in the context of the hospitals studied and the occurrence of prion diseases in Nepal. Firstly, none of the hospitals included in the study were performing neurosurgical procedures. Secondly, when a literature search was done, no literature reporting cases of prion disease in Nepal was found. These conditions, along with many others, could have led to such an unawareness among healthcare workers in these hospitals. However, this cannot simply rule out the possiblility of occurrence of prion diseases in Nepal. Cases of CJD, a type of prion disease, have been documnted in the northern part of the neighbouring country India (Biswas *et al.*, 2013; Mehndiratta *et al.*, 2001). Contaminated neurosugical instruments have been identified as a source of prions for a small propotion of reported cases of iatrogenic CJD globally (Brown *et al.*, 2012). There are higher-level public and private hospitals in Nepal doing neurosurgical procedures. Though the findings of this study cannot be generalised directly to higher-level hospitals, the fact that very few healthcare workers in primary and secondary hospitals knew about prions may be relevant to higher-level hospitals as well. The WHO has advised some changes in routine procedures for decontamination of medical devices likely to be contaminated with

prions (WHO, 1999). There is clearly a need to educate healthcare staff (specially those working in higher-level hospitals) about prions and such decontamination procedures.

8.4.2.8 Healthcare workers' recommendations for improvement

Recommendations made by healthcare workers for improvement of sterilization and reuse of medical devices in their hospitals were not just focussed on one particular area. Indeed, the recommendations were diverse, and aligned with different components of the quality management system, indicating a need for an overall improvement of the system. The most frequent use of the term 'training' by healthcare workers indicates their greater reliance on training. Studies have also shown that training in the area of infection control/prevention are effective in improving knowledge and practices of healthcare workers (Erkan, Fındık & Tokuc, 2011; Huang & Wu, 2008). However, Calabro, Bright and Kouzekanani (2000) found that infection control training was not effective in long-term retention of infection control knowledge. It is important to explore the short-term and long-term effectiveness of infection control training in Nepal. Healthcare workers' attitudes towards training will also be discussed in Section 8.4.3.2.

8.4.2.9 Sterilization during emergencies

Some hospitals cannot use their regular sterilizers or autoclaves in certain situations, including breakage or malfunction of the equipment. Healthcare workers were asked which alternative sterilization methods they use until their autoclave is repaired or replaced with a new one. Responses indicated that hospitals depend on lower level decontamination techniques in such situations, boiling being the most frequently reported interim method. A few healthcare workers also reported sun drying as one of the interim methods. Though chemical methods were commonly reported by healthcare workers as an interim method, many of them didn't specify which chemical they use in such situations. Indeed, chemicals can sterilize medical devices only if they are used properly. Proper use of glutaraldehyde has already been discussed in previous section (Section 8.4.2.3).

Healthcare facilities will not be able to use their regular sterilizers or autoclaves in some disastrous situations, for example, earthquakes, floods and landslides. Adverse effects such as

power loss, structural damage, evacuation and inability of staff to arrive at the facility can halt routine sterilization procedures. In 2015, Nepal experienced an earthquake of 7.8 magnitude. The earthquake completely destroyed 446 public health facilities including five district hospitals (National Planning Commission - Government of Nepal, 2015). Immediately after the earthquake, routine healthcare services were provided in tents where facilities were completely damaged or spaces were not enough for meeting increased healthcare demand. In cases of such humanitarian emergencies, the frequency of reuse of medical devices usually increases as a consequence of the increased demand for healthcare. Because of interruption of routine sterilization procedures, healthcare workers may be compelled to use interim options for reprocessing and reuse of medical devices. Indeed, the interim options reported by healthcare workers in this study were mostly suboptimal options. Specific policies and plans addressing sterilization and reuse of medical devices during disasters are essential. Conducting a risk assessment can prove useful in identifying the readiness of hospitals to undertake proper reprocessing of medical devices during such events (Duro, 2015). Assessments can include potential negative outcomes of an event, planning for the event and possible solutions.

A few doctors mentioned the use of broad spectrum antibiotics for minimising the risks of device-associated infections during emergency situations. This opinion indicates a possible association between poor sterilization of medical devices and overuse of antibiotics. However, this area needs more detailed exploration. According to Holmes *et al.* (2016), evidence has shown that overuse of antibiotics in humans is one of the key factors contributing to the emergence of antimicrobial resistance. Moreover, poor sterilization practices can further intensify transmission of resistant microorganisms.

8.4.3 Attitudes

Overall, the attitudes of healthcare workers towards issues related to decontamination and reuse of medical devices was found to be positive. However, only a small proportion (16.10%) of healthcare workers strongly agreed that the number of staff involved in decontamination of medical devices in their hospital was adequate and only 30.10% strongly agreed that deviation from routine reprocessing procedures for medical devices is not required when the devices had been used in patients with HIV.

Responses to attitude questions about patient safety (A1), decontamination of medical devices (A2), availability of sterilizers and supplies (A4), monitoring (A5), and staffing (A9) were not significantly associated with different independent variables including duration of healthcare work, healthcare profession, infection control training, employment status, and practice of autoclave operation. However, responses to all other attitude questions (A3, A6, A7, A8, A10, A11, and A12) were associated with at least one of the independent variables.

8.4.3.1 Attitudes towards policies

The attitudes of healthcare workers towards policies and standards were similar to the findings of a study conducted by Sukhlecha *et al.* (2015) in a tertiary hospital in western India. Sukhlecha *et al.* (2015) found that 84.3% of healthcare workers (including final-year students and interns, nurses, laboratory technicians and sanitary staff) strongly agreed or agreed that sterilization guidelines/policy in their hospital were useful. In our study, 80.8% of healthcare workers in primary and secondary hospitals indicated positive attitudes (5, 6 or 7 in 7-points rating scale) towards written policies and standards about decontamination of medical devices. This comparability was found despite the differences in contexts, study participants and structures of the attitude questions between the two studies. In primary and secondary care hospitals in Nepal, office assistants (autoclave operators) were less likely to have a positive attitude towards policies and standards compared to nurses. The level of education of office assistants ranged from illiteracy to a maximum of year 10 (class 10) of school education. Because of their very poor education level, office assistants may have been unlikely to recognise the importance of policies and standards. Despite this, all of the office assistants included in this survey were autoclave operators and were apparently responsible for implementing policies and standards for decontamination of medical devices.

8.4.3.2 Attitudes towards training

The majority of healthcare workers (89.0%) strongly agreed that training on the operation of sterilizers/autoclaves helps ensure adequate sterilization of medical devices. At the same time, in response to an open ended question about the improvement of sterilization and reuse of medical devices, healthcare workers used the term ‘training’ most commonly. Healthcare

workers who reported prior training on infection control/prevention were less likely to have a positive attitude towards training in the operation of sterilizers/autoclaves. This attitude could have been related to the perception among healthcare workers about the usefulness of the training they had received before. This finding indicates a need for exploring the effectiveness of training on infection control/prevention or related fields. Likewise, compared to nurses, doctors were less likely to have a positive attitude towards training in the operation of sterilizers/autoclaves.

8.4.3.3 Attitudes towards cleaning

Irrespective of their experience, healthcare profession, prior infection control training, employment status, or practice of autoclave operation, most of the healthcare workers (79.6%) strongly agreed that cleaning before sterilization is a necessary process. However, differences were found in attitudes between staff categories regarding the cleaning of visibly unsoiled medical devices. Compared to nurses, paramedics were more likely to agree that visibly unsoiled derives do not need to be cleaned before sterilization. As reported earlier in the knowledge section (Section 8.4.2), paramedics were more likely to give incorrect answers to most of the knowledge questions. Negative attitudes of paramedics towards cleaning of visibly unsoiled medical devices could have resulted from their poorer knowledge on reprocessing of medical devices compared to nurses. On the other hand, permanent staff were less likely to agree that cleaning before sterilization is not required for visibly unsoiled medical devices.

8.4.3.4 Attitudes towards being treated as a patient

Doctors were less likely to feel safe being treated as a patient using medical devices sterilized in their hospital, compared to nurses. Doctors have a central role in patient management in hospitals. Their minimum level of educational qualification is a bachelor's degree in medicine and/or surgery. Paudyal *et al.* (2008)found that doctors in Kathmandu (the capital city of Nepal) were more likely to have knowledge about the transmission of microorganisms compared to nurses, adjusted for age, working abroad, and infection control training (OR = 4.39; 95% CI 1.67 - 11.45; p = 0.003). A certain level of apprehension could exist among doctors about the sterility of medical devices used in their hospital. This could

have resulted in a less positive attitude among doctors towards safety while being treated as a patient using medical devices sterilized in their hospitals. Indeed, this attitude reflects the untrustworthiness of sterilization of medical devices in the hospitals.

8.4.3.5 Attitudes towards HIV and reuse of medical devices

Of the healthcare workers participating in the survey, 63% strongly agreed that every patient attending healthcare facilities must be considered potentially HIV positive. This finding was not different from the findings of some previous studies. In a survey conducted among dentists in Mexico city, 60% of them responded as 'of course' to the statement (Maupomé *et al.*, 2000). Similarly, 90% of Iranian dentists agreed with the statement (Askarian *et al.*, 2006). This attitude towards HIV transmission complies with the principles of universal/standard precautions for all patient care (CDC, 1988; CDC, 2017b; WHO, 2007c). If all patients attending healthcare facilities are considered potentially HIV positive, there won't be a need to treat HIV-positive patients differently. The same principle applies with reprocessing of medical devices as well, i.e. medical devices that had been used for HIV-positive patients do not need to be reprocessed differently, but only 30.1% of healthcare workers strongly agreed that deviation from routine reprocessing procedures for medical devices is not required when the devices had been used in patients with HIV. However, this attitude towards HIV-contaminated medical devices was not significantly associated with their opinion of considering all patients potentially HIV-positive. The negative attitude towards HIV-contaminated medical devices among the majority of healthcare workers could be a manifestation of HIV-related stigma and discrimination. Similar manifestations of stigma were reported by some other studies (Mahendra *et al.*, 2007; Nyblade *et al.*, 2009), for example, 97.2% of healthcare workers in rural north India agreed that it is necessary to take extra infection control precautions for patients with HIV (Kermode *et al.*, 2005). The study reported here found that staff with longer healthcare experience were more likely to believe that deviating routine reprocessing procedures is necessary for HIV-contaminated medical devices, adjusted for current employment status, infection control training, healthcare profession and practice of autoclave operation. On the other hand, in comparison to permanent staff, temporary staff were more likely to believe that deviating the routine reprocessing procedures is necessary, adjusted for other variables (see Table 8.17). These

findings emphasize the importance of complete education on standard precautions and HIV transmission for healthcare workers.

CHAPTER 9. DISCUSSION

Determining the effectiveness of moist-heat sterilization of medical devices in three different hospital categories (i.e. district-level hospitals, district hospitals and zonal hospitals) was the key objective of this study. Using biological indicators (containing 1.3×10^6 spores of *Geobacillus stearothermophilus*), this study found that 71.0% (95% CI 46.8% - 87.2%) of moist-heat sterilization cycles in primary and secondary care hospitals in Nepal were ineffective in killing the spores. Though the 95% confidence interval of the percentage of ineffective sterilization was quite wide, the lower bound of the confidence interval, i.e. 46.8%, was higher than the previously reported failure rates in any other countries studied (Table 3.1). The high percentage of ineffective sterilization cycles in hospitals in Nepal means it is very important to discuss the risks of transmission of infections, i.e. HAIs, via reusable medical devices reprocessed in these hospitals. It is also important to describe possible factors associated with such a high rate of steam sterilization failures. Finally, discussing and formulating ways to correct high steam sterilization failure rates is crucially important for reducing the probability of transmission of infections associated with reusable medical devices in Nepal. All of these topics will be covered in this chapter. Additionally, the strengths and limitations of this study will be discussed, and recommendations for future research will be made.

9.1 Significance of a High Rate of Sterilization Failure

The rate of steam sterilization failure in this study was obtained using self-contained biological indicator vials, each of which contained 1.3×10^6 spores of *Geobacillus stearothermophilus*. Mathematically, to obtain a universally accepted SAL of 10^{-6} (Section 2.4), only one biological indicator vial should show bacterial growth after exposing 10^6 such vials to a sterilization process. Unfortunately, overall 71.0% of the indicator vials (i.e. 71.0% of the sterilization cycles) showed growth after exposing them to the moist heat sterilization processes in the hospitals in Nepal. The failure rate is far too high compared with the universally accepted SAL.

This study found that none of the hospitals was monitoring the steam sterilization processes using biological indicators (Section 7.2.5). Despite this, medical devices are being

reprocessed and reused for patients attending these primary and secondary care hospitals in Nepal. In this context, it is important to interpret the sterilization failure rate found in this study in terms of the possibility of a medical device being unsterile after exposure to a failed steam sterilization process. The possibility of a medical device being unsterile is dependent on a number of critical control points in a reprocessing cycle. The risk factors which determine the possibility of a medical device being unsterile after a reprocessing cycle, and the safety factors which determine the possibility of sterilization of a medical device after a reprocessing cycle for the primary and secondary care public hospitals in Nepal can be summarized as shown in Figure 9.1.

The rate of the steam sterilization failure reported in this study is based on the biological indicator which contained more than a million spores of *Geobacillus stearothermophilus* which are more resistant to inactivation methods than other forms of microorganisms such as vegetative bacteria. The actual number and types of microorganisms present on the medical devices in the hospitals included in this study are not known. However, from previous studies (Section 2.2.1) reporting microbial load on used medical devices, it can be assumed that the microbial loads present on the used medical devices are smaller than the load in the biological indicators. On the other hand, the actual microbial load on a used medical device will comprise different forms of microorganisms including both the vegetative (sensitive) and spore (resistant) forms. In summary, the microbial load present on the medical devices is likely to be more susceptible to the inactivation methods than the microbial load in the indicators.

Cleaning medical devices (before sterilization process) can also reduce microbial load significantly, if carried out properly. Both the manual and automatic cleaning processes have been proven to be effective in reducing the microbial load on the medical devices if carried out properly (Alfa *et al.*, 2006; de Souza Evangelista *et al.*, 2015). However, the cleaning processes followed in Nepal were not uniform within and across the hospitals (Section 7.2.2). The cleaning processes ranged from the use of tap water to a combination of procedures including disinfection (with disinfectant), washing (with detergent/soap) and rinsing (with tap water); all of these procedures were manual. Indeed, the effectiveness of the cleaning processes followed in these hospitals is not known. However, overall compliance with the recommended cleaning practices was 45.8%, i.e. on average, only 45.8% of the recommended cleaning practices were followed by the hospitals (Section 7.3). In this context,

the cleaning processes are less likely to reduce the microbial load on the medical devices as effectively as the processes reported in previous studies (Alfa *et al.*, 2006; de Souza Evangelista *et al.*, 2015).

Drying of medical devices also has an effect on microorganisms, known as desiccation, which reduces the load of viable microorganisms on medical devices to some extent. The effect of drying on microorganisms varies according to the type of microorganisms present on the devices. Enveloped viruses such as HIV are highly susceptible, methicillin-resistant *Staphylococcus aureus* is moderately susceptible, whereas HBVs are resistant to desiccation (Donskey *et al.*, 2014; Rutala & Weber, 2007). In summary, cleaning and drying significantly reduce the number of viable microorganisms present on the used medical devices but the degree of reduction depends on the procedures applied and the types of microorganisms present.

The most important and key process in reducing the microbial load on medical devices is sterilization. In this study, 71.0% of the sterilization cycles were ineffective at killing 1.3×10^6 bacterial spores contained in a biological indicator. This result was obtained when the biological indicators were wrapped separately in a fashion which simulated the wrapping of the medical devices in the sterilization load (Section 4.6.1). However, the effectiveness of the sterilization process in killing microorganisms in the actual packages of medical devices is dependent on the characteristics of the medical devices and of the package (i.e. type, dimensions and contents). Killing microorganisms in porous loads and in medical devices with narrow channels (e.g. dental hand piece) is more difficult than killing microorganisms on solid devices. This is because of poor penetration of steam into narrow channels, specifically when simple pressure-cooker type autoclaves or gravity displacement autoclaves are used (Van Doornmalen *et al.*, 2013; Winter *et al.*, 2017a; Winter *et al.*, 2017b). This study found that 91.9% of the steam sterilization cycles included porous items and 46.4% of the cycles included devices with lumens or tubular structures in the sterilization loads. All of the autoclaves used for sterilizing medical devices were either pressure-cooker type or gravity displacement autoclaves (Section 5.4.4). This context indicates that the steam might not have penetrated into all parts of a medical device package as effectively as into the indicator tubes. Therefore, the actual killing effect of the steam inside the medical device packages might have been less than inside the indicator packages.

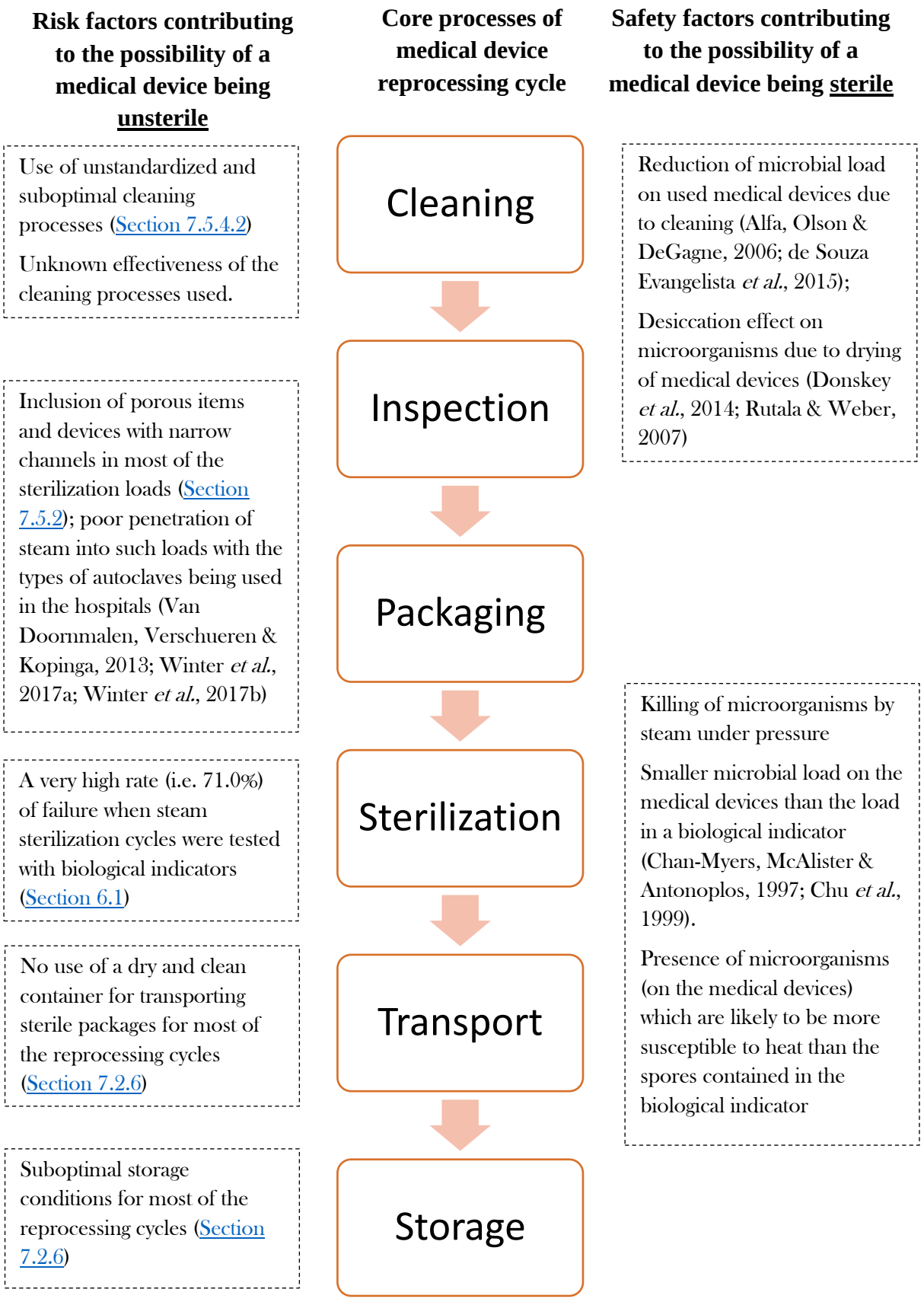

Figure 9.1: Risk and safety factors likely to determine the sterility of medical devices in hospitals in Nepal

In ideal conditions, a negative (i.e. accepted) biological indicator test result (killing of 1.3×10^6 bacterial spores in an indicator tube) provides a large safety margin, as medical devices would carry a smaller microbial load and would not be likely to harbour resistant organisms in such a high number. Medical devices can be reused with a great assurance of safety after having an accepted biological indicator test result, but in this study a large proportion (71.0%) of steam sterilization cycles did not have an accepted result. A pertinent concern arises from this finding – do the medical devices obtained from such failed sterilization processes in the hospitals harbour viable microorganisms? It cannot be guaranteed that medical devices harbour viable microorganisms after a failed result with the biological indicator because they can have a smaller bioburden and the microorganisms present can be more susceptible to the sterilization process. On the other hand, with a positive (failed) result of the biological indicator, no assumptions can be made about the extent to which microorganisms present on the medical devices are killed. Rather, with such a high failure rate, there is a reasonable possibility of a microorganism surviving on a medical device after a failed sterilization process. This possibility is further supported by suboptimal cleaning procedures being followed and use of pressure-cooker type or gravity displacement autoclaves for sterilizing porous loads and medical devices with narrow channels. Additionally, suboptimal conditions for the storage of sterilized medical devices can increase the possibility of recontamination of the medical devices.

In summary, in the context of primary and secondary care hospitals in Nepal, a positive biological indicator test result, while not proving the presence of living microorganisms, indicates a fair possibility of the presence of living microorganisms on a medical device.

9.2 The Risk of Transmission of a Pathogen

Further to the discussion above about the possibility of contamination of a medical device after a failed sterilization cycle, it is very important to understand the risks of transmission of infectious diseases due to the reuse of a contaminated medical device in the context of Nepal. The risk of transmission of an infectious disease through a contaminated medical device is dependent on additional factors; including the prevalence of the disease in the population and the infectivity of the pathogen through a route of transmission (Donskey *et al.*, 2014; Rutala & Weber, 2007). These factors additionally alter the risk of transmission of a disease through

a contaminated medical device. The likelihood of contamination of a medical device with an infectious agent by patients or healthcare workers is reliant on the prevalence of the infectious disease in the population.

Rutala and Weber (2007) presented a very low risk (about 1 in 10^{10}) of transmission of HBV after a failure to follow recommended practices for sterilization of specula in an obstetrics-gynaecology clinic in the US. Indeed, such a low risk was obtained after considering the prevalence of HBV in the US population of 0.5% (i.e. 5:1000), risk of transmission of HBV via mucous membrane contact 1:100, likelihood of non-sterilized speculum used 1:5, efficacy of washer/disinfector 99.999% (i.e. risk 1:100,000) and effect of HBV drying 1:1. If these risk factors are reviewed in the context of Nepal, the average efficacy of manual cleaning of medical devices in the primary and secondary care hospitals is likely to be considerably less than the efficacy of the washer/disinfector considered above. Additionally, the likelihood of inadvertent use of non-sterilized medical devices could be higher in the context of Nepal because of a sterilization failure rate of 71.0%. Therefore, the risk of transmission of infectious diseases due to the use of inadequately sterilized medical devices could be much higher than the risk reported by Rutala and Weber (2007). Reported rates of some infections in hospitals in Nepal also support this possibility (Shrestha & Bhattarai, 2006). The prevalence and the infectivity of different pathogens can vary greatly and the effect of these factors on the risk of transmission should always be considered. In summary, the reuse of medical devices in hospitals in Nepal carries risks of transmission of infectious diseases to patients and healthcare workers, due to inadequate reprocessing and sterilization of these devices.

9.2.1 The risk in different hospital categories

The primary and secondary care hospitals included in this study represented three different tiers of public hospitals in Nepal, i.e. district-level hospitals, district hospitals, and zonal hospitals. The rate of steam sterilization failures for these three types were 90.0%, 66.7% and 66.7% respectively. However, as discussed in Section 6.1, these failure rates across hospital levels were not statistically significantly different ($p = 0.51$). However, the range and number of invasive healthcare procedures carried out in these hospitals can also have effects on the risk of transmission of infections associated with reusable medical devices. As discussed in

Section 1.5, the district-level hospitals are the smallest public hospitals in the country, carrying out less invasive healthcare procedures including minor surgical procedures. Therefore, the likelihood of contamination/infection of patients via the medical devices is likely to be lower compared to larger hospitals such as district hospitals and zonal hospitals where more invasive healthcare procedures are performed. Most of the district hospitals provide a broader spectrum of healthcare services, with some major surgical procedures requiring a separate operating theatre, such as caesarean sections, appendicectomies, herniorrhaphies/hernioplasties and cystolithotomies. Sterile tissues or body parts of patients come in contact with the medical devices easily during such procedures. Therefore, the risk of transmission of pathogens might be higher with these procedures than with minor surgical procedures when the sterilization of medical devices is inadequate. The zonal hospitals perform some more complex surgical procedures such as surgeries related to dentistry, orthopaedics and ear, nose and throat (ENT), where the risk of infection might be higher if the medical devices are inadequately sterilized. Infections in such cases might lead to serious complications resulting in increased morbidity and mortality.

Risk of infections associated with reusable medical devices is not limited to surgical procedures. There are many other clinical procedures which demand reuse of medical devices after adequate reprocessing and sterilization. In the settings of primary and secondary care hospitals in Nepal, such procedures include, but are not limited to: prenatal care, delivery of babies, postnatal care, dental care, eye care, immunization activities, family planning services, and diagnostic laboratory procedures. A review by Zaidi *et al.* (2005) reported that rates of hospital-acquired neonatal infections in developing countries are 3-20 times higher than in developed countries. The review mentioned "failures in sterilization/disinfection or handling/storage of multi-use instruments, equipment and supplies, leading to contamination" and "re-use of disposable supplies without safe disinfection/sterilization procedures" as two of the critical points linked with the hospital-acquired neonatal infections in these countries. As the rates of sterilization failure in primary and secondary care hospitals in Nepal are quite high, there is a clear possibility of transmission of pathogens to neonates through the medical devices. Thapa *et al.* (2013) reported caesarean section (OR 1.95; 95% CI 1.15 – 3.31) as one of the predictors of neonatal sepsis in a neonatal intensive care unit (NICU) of a tertiary care hospital in Nepal. Studies from other countries have reported that improvement in infection control practices, including sterilization and disinfection, can contribute to the reduction of hospital-acquired neonatal septicaemia (Gill *et al.*, 2009; López *et al.*, 2013).

9.3 Inadequate Reprocessing and Antimicrobial Resistance

Documentation of HAIs is poor in Nepal. The few published studies reported higher rates of SSIs in hospitals in Nepal compared with the reported rates in developed countries (Chapagain *et al.*, 2017; Giri *et al.*, 2008; Giri *et al.*, 2013; WHO, 2011). However, none of the reports were from the hospital categories included in this study; the reports were rather from larger hospitals, e.g. tertiary care hospitals. Looking at the sterilization failure rates and the compliance of the hospitals with recommended reprocessing practices, the rates of SSIs and other device-associated infections are likely to be quite high. Indeed, extensive prophylactic use of antibiotics could have played a very important role in limiting the occurrence of such infections. Studies reported the prophylactic use of multiple antibiotics in almost all of the patients undergoing major surgical procedures surgeries in different hospitals in Nepal. Giri *et al.* (2013) documented the use of a number of antibiotics as a prophylactic measure in all (i.e. 100%) of the patients who had undergone abdominal surgery in a teaching hospital in Nepal. In another study in a different teaching hospital, 94.7% of patients who had undergone general surgical procedures were found to be receiving antibiotic prophylaxis; mean duration of antibiotic use was 6.3 days in this study (Giri *et al.*, 2008). Shrestha *et al.* (2016) reported the prophylactic use of antibiotics in 99.8% of all surgeries in another teaching hospital; single dose preoperative prophylaxis was used for 10.6% of the cases and multiple-dose postoperative prophylaxis was used for 89.4% of the cases. In a tertiary care hospital in Nepal, Das *et al.* (2005) found that 19.4% of the total antibiotic prescriptions were made for prophylaxis whereas 73.3% of the prescriptions were for therapeutic purposes; in 86.5% of the prophylactic prescriptions, antibiotics were prescribed for more than 3 days. WHO strongly recommends using a single dose of an antibiotic as a preoperative prophylaxis (within 120 minutes before incision) when indicated (WHO, 2016b).

In this study, when healthcare workers were asked about the measures taken if an autoclave in a hospital did not function properly, some physicians mentioned the use of a combination of broad-spectrum antibiotics both before and after a surgery as a prophylactic measure to prevent infections (Section 8.2.10). This response meant that they recognised the increased infection risk resulting from ineffective sterilization. This finding also indicates how substandard infection control practices including reprocessing of medical devices in the

hospitals can promote widespread use of antibiotics. The extensive use of antibiotics in human beings leads to increased resistance to antibiotics (including many life-saving antibiotics) in microorganisms rendering the treatments of some infections impossible (Holmes *et al.*, 2016; Review on Antimicrobial Resistance, 2016). Studies in Nepal reported that about 65% of the bacterial isolates from SSIs in tertiary care hospitals were multi-drug resistant (Bhatt *et al.*, 2014; Raza, Chander & Ranabhat, 2013). The authors of these studies considered bacteria resistant to two or more classes of antibiotics as multidrug resistant. Therefore, on one hand, inadequate reprocessing and sterilization of medical devices can lead to transmission of drug-resistant pathogens from one person to another; on the other hand, it may also promote extensive use of antibiotics and consequently the development of antimicrobial resistance in pathogens.

9.4 Factors Associated with a High Failure Rate

In order to improve the effectiveness of steam sterilization practices in the hospitals, it is crucial to understand possible factors associated with steam sterilization failures. Understanding such factors will help hospitals to identify the interventions required to minimize steam sterilization failures.

The failure or success of a steam sterilization cycle primarily depends on the autoclave and its operation. Additionally, characteristics of medical device packages may influence the failure or the success of the sterilization cycle. In this study, the effectiveness of the steam sterilization cycles was determined by using indicators which were wrapped using the wrapping methods used for the actual medical device packages, but were kept external to the actual medical devices packages. Therefore, the factors within the actual medical device packages were not likely to have any impact on the results of the biological and the chemical indicators in this study (Section 4.6.1). In this context, time and temperature (determined by the pressure in the autoclave; for example, 15 psi = 121°C) are the key factors determining the effectiveness of an autoclave cycle. However, other factors such as quality of steam (Section 2.5.1) and wrapping methods also need to be considered.

Using a Logistic Regression model for complex samples (Section 6.6), this study found that only pressure (an indicator of temperature) and autoclave type were associated with

sterilization failure in the primary and the secondary care hospitals in Nepal. The holding period (i.e. time), evenness of pressure during the holding period, and barrier system used to wrap the medical devices were not associated with sterilization failure. This finding must be interpreted very cautiously and cannot be generalized universally. In ideal settings, other factors such as time have a very clear association with the effectiveness of a sterilization cycle (Perkins, 1956). However, in the context of the primary and the secondary care hospitals in Nepal, this finding can have very important implications. Failure to reach the required temperature during autoclaving and use of pressure-cooker type autoclaves were associated with the steam sterilization failures in these hospitals. Therefore, for improving the effectiveness of steam sterilization in these hospitals, these two factors need be considered primarily.

Pressure/temperature:

For killing all forms of microorganisms using a steam sterilization cycle, attainment of the required temperature (required pressure) is the most fundamental principle. Different temperatures such as 121°C, 134°C and 144°C are recommended for sterilizing reusable medical devices. The temperature used for sterilizing medical devices determines the exposure period required for sterilizing medical devices. If a higher temperature is used, a shorter exposure period is required for sterilizing the medical devices. The Reference Manual for Infection Control and Healthcare Waste Management in Nepal recommends a temperature of 121°C for 30 minutes for sterilizing wrapped medical devices and a temperature of 121°C for 20 minutes for sterilizing unwrapped medical devices (NHTC - Ministry of Health and Population - Government of Nepal, 2015b). The pressure inside the sterilization chamber should reach 15 psi (above atmospheric pressure) to achieve a sterilization temperature of 121 °C. Only about 46% of the autoclave cycles in this study reached a pressure of 15 psi or above (Section 6.4). Surprisingly, only 3 of the 13 hospitals included in this study achieved a sterilizing pressure of 15 psi or above for all of the autoclave cycles tested. This clearly indicates that 10 of the 13 hospitals were either using faulty autoclaves or operating the autoclaves inappropriately.

This study found the use of non-validated equipment, lack of spare parts (including gaskets, safety valves and pressure valves) and manufacturer's instructions, lack of equipment maintenance, and absence of a mechanism for reporting incidents in all of the hospitals

included in this study. There were no mechanisms for identifying a faulty autoclave in any of the hospitals. These contexts indicated a high likelihood of faulty equipment in these hospitals. Also, support staff were involved in the operation of autoclaves for 97.0% of the reprocessing cycles; they were statistically significantly less likely to know the recommended temperature (i.e. 121°C) for sterilization in comparison with the nurses ($p = 0.002$). In addition, there is no provision of specific training on the operation of autoclaves for healthcare workers in Nepal. Therefore, the inappropriate operation of autoclaves and failure to achieve the recommended temperature and pressure were likely in these hospitals.

Autoclave type

Autoclave type was the second factor which was statistically significantly associated with the failure of steam sterilization. None of the autoclaves used in the hospitals were pre-vacuum autoclaves. Only 3 of the 24 autoclaves used in the hospitals were gravity (downward) displacement autoclaves. All of the remaining autoclaves were basic pressure-cooker type autoclaves. As discussed in Section 2.4.1.2, pressure-cooker type autoclaves are the most primitive type of autoclaves available and they have very poor air displacement capabilities (Perkins, 1956). Devices sterilized in these autoclaves are supposed to be used immediately after sterilization (McDonnell & Sheard, 2012). These autoclaves are not appropriate for porous loads, medical devices wrapped in a sterile barrier system and medical devices having lumens or complex tortuous paths because they are not effective in displacing air present inside such loads or devices with saturated steam. Gravity displacement autoclaves are considered better than pressure-cooker type autoclaves in terms of displacement of air with steam. However, these autoclaves also are not considered appropriate for these types of medical devices as they also are not very effective in complete displacement of air with the steam (Huys, 2010). Indeed, this study found that for all of the reprocessing cycles, reusable medical devices were enclosed within a barrier system; none of the devices or supplies were sterilized without keeping them inside a barrier system. Medical devices were either single wrapped with a wrapping material, double wrapped, kept inside a reusable container, or kept within two more barrier systems. For the purpose of this study, the same barrier systems were used to wrap the biological indicators when testing the autoclave cycles in the hospitals. As could be anticipated, the pressure-cooker type autoclaves were found to be statistically significantly more likely to be associated with failed results compared with the downward displacement autoclaves.

Importantly, for 91.9% of the reprocessing cycles, porous items were included in the sterilization load, and for 46.4% of the reprocessing cycles, medical devices with lumens or tubing were included in the sterilization load. Displacement of dry air from such items and penetration of the steam into them becomes even more difficult while using non-vacuum gravity displacement or pressure-cooker type autoclaves. Though this study did not specifically determine the effectiveness of these autoclaves in killing microorganisms inside the lumens and the tubing of actual medical devices, Winter *et al.* (2017b) recently demonstrated that non-vacuum autoclaves were not reliable in achieving the required sterilization conditions inside lumened medical devices such as dental hand-pieces.

Exposure period

In principle, time (i.e. holding period) is clearly linked with the killing of bacterial spores in the biological indicator when the required temperature/pressure of the autoclave is achieved (Van Doornmalen & Kopinga, 2009). More than half of the sterilization cycles observed in the hospitals in this study did not achieve the minimum required pressure (i.e. 15 psi above atmospheric pressure) required for the sterilization of medical devices. The lack of association of time with the effectiveness of sterilization cycle obtained in this study is likely to be because of the inability of most of the sterilization cycles to achieve the required temperature/pressure. When the maximum pressure/temperature achieved during the holding period of a sterilization cycle is low (e.g., less than 10 psi), it takes much longer to kill all the spores in a biological indicator (Bigelow & Esty, 1920; Perkins, 1956; Van Doornmalen & Kopinga, 2009). Indeed, the holding periods observed during the sterilization cycles were not statistically significantly associated with the observed maximum pressure achieved during the period ($p = 0.29$). A similar finding was obtained when healthcare workers were asked in a survey about the sterilization temperature and the holding period recommended for the wrapped medical devices. No statistically significant association was found between the temperatures and the holding periods stated by the healthcare workers. There are practices which are recommended for ensuring the exposure of medical devices to steam for the required period of time when the required temperature/pressure is achieved. Such practices include using a timer to monitor the holding period, starting time-keeping only when the required pressure is achieved, recording different parameters of a sterilization cycle (such as temperature, pressure, holding period, date, load number and operator), and reviewing the

parameters after each run. The compliance of the hospitals with such practices was very poor (Section 7.2.5)

The findings of the study clearly indicate that there was no systematic practice of using the correct temperature and time for sterilizing medical devices in the hospitals. Similarly, there was no clear and uniform understanding among the healthcare workers about the temperature and time required for sterilization. Hospitals should achieve the core requirements of the temperature (or the pressure) and the time for ensuring the effectiveness of steam sterilization. These requirements can only be achieved if all the processes of the quality management system of the medical device reprocessing function effectively (Section 2.6).

9.5 Standard Practices

Sterilization is the most crucial process of the medical device reprocessing cycle. Sterility of the reusable medical devices ultimately depends on the effectiveness of the sterilization process. However, for a sterilization process to be effective, all the other processes of a reprocessing cycle preceding sterilization i.e. cleaning, inspection and packaging of the used medical devices need to be performed following standard practices. On the other hand, the processes succeeding sterilization i.e. transport, storage and use of sterilized packages need to be managed in such a way that no contamination of the devices takes place following sterilization. This study found poor compliance of the hospitals with the practices recommended for all the processes of a reprocessing cycle.

There were areas of medical device reprocessing about which most of the healthcare workers had basic knowledge or positive attitudes, but actual practices around those issues were not adequate nor standardized. The majority of the healthcare workers working in the hospitals (about 80.0%) strongly agreed that cleaning before sterilization is a necessary process and medical devices need to be cleaned even if they are not visibly soiled (Section 8.3.7). However, only 46.0% of the practices recommended for cleaning were followed by the hospitals. Such poor compliance with the recommended cleaning practices could have been related to the involvement of the office assistants in cleaning the medical devices. The office assistants either had a very low level of formal education or were illiterate. For 98.4% (95% CI 88.3% - 99.8%) of the reprocessing cycles, office assistants were involved in the cleaning

process. Inadequate training and monitoring also could have contributed to the noncompliance.

One of the important issues highlighted by this study related to the cleaning of medical devices particularly is inconsistencies in the manual cleaning of medical devices within and across the hospitals (Section 7.2.2). The Reference Manual for Infection Control and Healthcare Waste Management in Nepal provides some guidance on the cleaning of medical devices (NHTC - Ministry of Health and Population - Government of Nepal, 2015b). The cleaning procedure recommended in the reference manual was found to be followed only for 53.6% (95% CI 30.5 % - 75.3%) of the reprocessing cycles. Indeed, the effectiveness of the procedure described in the reference manual is not clear. The manual recommends using hypochlorite solution for disinfecting medical devices immediately after use. However, the WHO no longer recommends pre-soaking used medical devices in a disinfectant solution before cleaning (Section 7.5.4.3). Household soaps or detergents were being used for cleaning medical devices in all of the hospitals. Guidelines and standards recommend using only those detergents which are specifically intended for use on medical devices (Standards Australia & Standards New Zealand, 2014; WHO, 2016a).

Revision of the current recommendation made by the reference manual could be the foremost step for improving the cleaning of medical devices in hospitals in Nepal. Preventive measures such as the use of PPEs during cleaning of medical devices and adequate vaccination of staff need to be promoted, and the practice of pre-soaking medical devices in hypochlorite solution before cleaning needs to be stopped. Hospitals should develop and implement procedures for selection and purchase of detergents specifically intended for cleaning of medical devices. Such detergents should be used according to the manufacturer's instructions. In case of hardening or drying of blood or exudates on the medical devices, enzymatic cleaning agents may also need to be used for effective manual cleaning (WHO, 2016a). Specific instructions from the manufacturer may also be required for the cleaning of some medical devices. All medical devices should be dried properly immediately after cleaning using non-linting towels, and the effectiveness of the manual cleaning needs to be established through visual inspection, which could be carried out with the help of a magnifier. Currently, automated and reliable techniques, such as ultrasonic cleaners and washer-disinfectors, are available for cleaning of medical devices. These techniques can be useful and efficient in larger hospitals

such as zonal hospitals. However, provision of skilled staff is essential for adopting such techniques.

As with the cleaning process, inconsistencies in the packaging of reusable medical devices were found in this this study (Section 7.2.4). Medical devices were single wrapped, double wrapped, kept inside a reusable sterilization container (steel drum which can be manually opened and closed), or packaged using a combination of two or more systems. The wrapping material used was always linen. The Reference Manual for Infection Prevention and Healthcare Waste Management recommends double wrapping medical devices with wrapping material (NHTC - Ministry of Health and Population - Government of Nepal, 2015b). The manual mentions the use of a rigid sterilization container (steel drum). However, it is not clearly stated when to wrap medical devices and when to put them inside the rigid container. Indeed, for 36.6% (95% CI 18.7% - 59.1%) of the reprocessing cycles, medical devices were first wrapped in a wrapping material and then kept inside a rigid metal container (drum with a lid) making a complex barrier system. This practice can provide better protection to the wrapped medical devices. At the same time, it can also present a greater barrier to the steam, and thus reduce the ability of the steam to penetrate into the internal parts of the medical devices. Additionally, moisture can be retained inside the rigid container after sterilization, leaving the wrapped packages moist. Interestingly, the primary hospitals (which use small pressure-cooker type autoclaves) were more likely to use complex barrier systems than the secondary care hospitals. The WHO no longer recommends using metal drums as a barrier system for sterilizing medical devices (WHO, 2016a). Indeed, a report on the sterilization arrangements in six different hospitals in the UK considered the steel drum as "an unsatisfactory piece of equipment" 60 years ago (The Nuffield Provincial Hospitals Trust, 1958). Drums similar to those described as unsatisfactory by the Nuffield report were still being used quite commonly in the hospitals in Nepal for non-vacuum autoclave cycles. Though the barrier systems used were not statistically significantly associated with the results of the biological indicators in this study, their exact effect inside the medical device packages is unclear.

As the practice of wrapping medical devices varied greatly between the hospitals in Nepal, there is a need to set criteria for using different barrier systems for packaging different sets of medical devices. All the barrier systems used in the hospitals need to be validated to ensure that the medical devices inside a barrier system can be sterilized by a sterilization technique.

The barrier systems also need to be evaluated for their ability to maintain sterility of medical devices. Nowadays, different wrapping materials, including disposable non-woven materials, are available for packaging medical devices. There are issues of cost, safety and environmental impact related to the use of disposable materials in place of reusable materials. Overcash (2012) published a review of studies and reported no statistically significant differences between the disposable and the reusable textiles used for surgical activities in terms of cost, safety and environmental impact. Therefore, it is advisable to continue to use woven fabrics, such as linens, for packaging medical devices in hospitals in Nepal. However, care should be taken about the deterioration of reusable fabrics over time because deteriorated fabrics may not provide adequate protection to the sterilized medical devices to prevent their microbial contamination. Rodrigues *et al.* (2006) reported that cotton fabric can be reused for a maximum of 65 times for packaging medical devices. It is also recommended that the use of steel drums for packaging reusable devices and materials in the hospitals be discontinued. If the use of a rigid container is unavoidable, such a container should be tested and validated for the sterilization process to be used, and also evaluated for its effectiveness in preventing microbial contamination of medical devices (Association of Perioperative Registered Nurses, 2007). Currently, different containment devices including organising trays, rigid containers and instrument cases are available; manufacturer's instructions need to be strictly followed when using such devices.

Adequate transport, storage and use of sterilized medical devices are crucial, not only for preventing recontamination of medical devices after sterilization, but also for preventing transmission of pathogens due to such recontamination. Studies have reported infections associated with the recontamination of medical devices during transport and storage (Dancer *et al.*, 2012) . The findings of this study indicate that there are clear possibilities of recontamination of sterilized medical devices in the primary and the secondary care hospitals in Nepal due to poor compliance with recommended transport and storage practices (Section 7.2.6). Such practices include inspecting sterile packages for integrity and reprocessing compromised packages, transporting sterile packages in a dry and clean container, and storing sterile packages in a separate clean area protected from dust, moisture, insects and extreme temperature. Furthermore, sterilized package obtained from about 90.0% of the sterilization cycles were moist or wet. When moist or wet sterile packages are stored in suboptimal storage conditions, the likelihood of recontamination of medical devices increases. At the same time, knowledge of the healthcare workers about wet sterilized packages of medical

devices was quite divided; only 37.4% of the healthcare workers strongly agreed that such packages are considered to be contaminated. This finding, along with the findings about transport and storage conditions, indicates that the possibility of contamination of medical devices does not end with a successful sterilization cycle in the primary and the secondary care hospitals in Nepal; contamination is possible even after a successful sterilization.

Shelf-life is another important aspect of the storage of sterilized medical devices. As discussed in Section 8.4.2.5, there is no standard recommendation about the shelf-life of sterilized medical devices. Rather, studies demonstrated that sterilized medical device packages can be stored in appropriate storage conditions until an event leading to possible contamination of sterilized medical devices occurs. As discussed before, the recommended practices for storing the sterilized medical devices were not followed for most of the reprocessing cycles (Section 7.5.8) in the hospitals included in this study. Moisture in sterilized packages favours entry and growth of microorganisms inside the sterilized packages and inadequate storage conditions increase the possibility of contamination of the sterilized packages. With the current situation of transport and storage conditions which might favour the entry and growth of microorganisms inside sterilized medical device packages, the shelf-life of the sterilized packages in these hospitals cannot be expected to be very long. In fact, the shelf-life of the sterilized medical devices recommended by the national Reference Manual for Infection Control and Healthcare Waste Management is 7 days (NHTC - Ministry of Health and Population - Government of Nepal, 2015b). Also, in this study, the majority of the healthcare workers (about 79.0%) answered 7 days when asked about the shelf-life of sterilized medical devices. However, a shelf-life of 7 days was not implemented strictly in the hospitals; this was indicated by the findings that sterilized packages were labelled with the date of sterilization for only 28.8% (95% CI 12.5% - 53.5%) of the reprocessing cycles and with the date of expiry for only 8.0% (95% CI 0.9% - 45.0%) of the reprocessing cycles.

Event-related shelf-life and time-related shelf-life of the sterilized packages have already been discussed in Section 8.4.2.5. In the current situation, event-related shelf-life seems irrelevant in the hospitals due to the wetness of the sterilized packages and inadequate storage conditions discussed before. At the same time, implementation of a very short shelf-life, such as a shelf-life of 7 days, will demand an increase in resources for more frequent sterilization of medical devices. If the current sterilization, transport and storage conditions were

improved, the shelf-life of the medical devices could be increased. An increase in shelf-life of the sterilized medical devices will bring a decrease in the frequency of medical device reprocessing cycles, and thus can be an economical approach for the reprocessing of reusable medical devices (Barrett *et al.*, 2003).

Improvement in the current sterilization, transport and storage conditions is a prerequisite for recommending a shelf-life longer than the currently recommended 7 days. Performing an assessment of the risk of contamination of sterilized medical devices is recommended before implementing a longer or event-related shelf-life. If recommended sterilization, transport and storage conditions are met, implementation of a longer shelf-life, such as 30 days, could be beneficial for the hospitals in Nepal.

9.6 Management and Support Processes

According to theories about quality in healthcare, the desired quality in a healthcare activity or service can be achieved only if relevant management and support processes related to the service are in place (Section 2.6). This study collected information related to the management and support processes of medical device processing in the hospitals. Findings about these processes are discussed in the following sections, and recommendations are made.

9.6.1 Guidelines and standards

The only documents providing guidance about the reprocessing and reuse of medical devices in Nepal are the training documents (reference manual, trainer's manual, and participant hand-book) developed by the NHTC - Ministry of Health and Population. However, a training document (only the participant hand-book) was available in only one of the hospitals. There were no hospital-specific guiding documents related to the reprocessing and the reuse of medical devices in the hospitals included in this study. Countries like Australia, New Zealand, UK and USA have standards specific to the decontamination and the reuse of medical devices. The standards help to ensure safety, reliability and quality of the decontamination processes (Bancroft, 2014). Guidelines and standards are normally implemented voluntarily. However, they are developed as a way of implementing some legal or mandatory requirements of a country (Bancroft, 2014). For example, in Australia, the

Therapeutic Goods Act forms a legal base for decontamination of medical devices whereas the Australia/New Zealand Standard on reprocessing of medical devices provides more specific interpretation and helps in the implementation of the act; the Medical Device Standards Orders work as a link between the act and the standard (Bancroft, 2014). No such legal base for reprocessing and reuse of medical devices could be identified in Nepal. None of the health related Acts and regulations approved by the Government of Nepal until April 2016 could be identified as applicable for the reprocessing and reuse of medical devices in Nepal (Government of Nepal, 2015; Government of Nepal, 2016). The recently approved "Health Technology Product and Medical Device Directive" does not include anything specifically about the sterility and reuse of medical devices (Office of the Prime Minister and Council of Ministers - Government of Nepal, 2017). However, the directive mentions that the Department of Drug Administration (DDA) is responsible for specifying national standards for health technology products and medical devices. The directive further mentions that the DDA should specify national standards based on the criteria specified by the WHO. So, there seems to be a very indirect or weak legal basis for ensuring adequate sterility of medical devices in Nepal. However, there are some national policy and strategy documents which address the quality of healthcare services and infection prevention in healthcare facilities in Nepal (Section 1.5.1).

There is a need for a firm legal basis in the form of legislation or directives to ensure adequate decontamination of reusable medical devices. National guidelines or standards describing minimum requirements for reprocessing and reuse of medical devices are also needed. Such guiding documents need to be in line with the current universal recommendations on medical device reprocessing. Each hospital should develop local procedures based on the guidance provided by the national guidelines or standards. Training packages need to be developed to implement the national standards and the local procedures.

9.6.2 Steering

In Nepal, the DDA, Curative Service Division - Ministry of Health, Management Division - Department of Health Services, and NHTC seem to be directly or indirectly involved with the issues related to medical devices and healthcare infection prevention and control (Department of Health Services - Ministry of Health - Government of Nepal, 2017; Ministry of Health -

Government of Nepal, 2017; NHTC - Ministry of Health and Population - Government of Nepal, 2015b; Office of the Prime Minister and Council of Ministers - Government of Nepal, 2017). However, there seems to be no clear division of responsibilities among these institutions about healthcare infection prevention and control including medical device reprocessing issues. Both government and the non-government institutions work in other countries in the area of healthcare infection prevention and control. Government organizations such as the CDC and U.S. Food and Drug Administration (FDA) are involved in the regulation and monitoring of infection prevention and control in the US (CDC, 2017a; FDA, 2017). The Health Quality and Safety Commission of New Zealand has been established by the New Zealand Government for the purpose of monitoring and improving healthcare quality and safety, including infection prevention and control. Non-government institutions such as the Association for Professionals in Infection Control and Epidemiology (APIC), Association of Perioperative Registered Nurses (AORN), Healthcare Infection Society (HIS), Infection Prevention Society (IPS) and International Federation of Infection Control (IFIC) work in the US, in the UK and globally in the area of infection prevention and control (Association of Perioperative Registered Nurses, 2018; Healthcare Infection Society, 2018; Infection Prevention Society, 2018; International Federation of Infection Control, 2018; The Association for Professionals in Infection Control and Epidemiology, 2018).

Hospital level entities are equally important in the prevention and control of infections in healthcare facilities. Such entities can take the forms of infection control committees, infection control teams, infection control officers, and/or infection control nurses (Rasslan, 2016). These entities are usually responsible for ensuring adequate reprocessing of medical devices as well. In a survey conducted by Ohara *et al.* (2013) among 17 leading hospitals in Kathmandu (the capital city of Nepal), only 7 hospitals self-reported the existence of an infection control committee; and only two of these reported regular meetings of infection control committees. On the other hand, a study comprising 169 acute-care hospitals in Europe reported the existence of a formal infection control programme, a multidisciplinary infection control committee, trained infection control nurses and trained infection control doctors in higher percentages, i.e. 72%, 90%, 80% and 74% respectively (Struelens *et al.*, 2006). Though this study did not collect information about the existence of infection control committees or similar entities in the primary and the secondary care hospitals in Nepal, it is quite unlikely that these hospitals have any dedicated entities overseeing the infection control activities including medical device reprocessing; this is because only about 41% of the

leading hospitals in the capital city of Nepal (also the largest city where better infrastructure and management of such hospitals are expected) self-reported the existence of such entities (Ohara *et al.*, 2013) .

A clear division of responsibilities related to infection control, including medical device reprocessing, is required at the national level. Responsibilities for medical device reprocessing can be divided into different domains such as the development of guidelines and standards, development and training of human resources, supervision and monitoring of medical device reprocessing in the hospitals, and continuous quality improvement. The findings of this study indicate that reprocessing of medical devices in the public hospitals in Nepal is haphazard and unregulated. A focussed and deliberate effort is required at the national level for an improvement in the reprocessing and reuse of medical devices in the public hospitals. Formation of an accountable government body responsible for national level steering and coordination of medical device reprocessing could be an entry point towards an improvement. At the hospital level, the formation of structures supporting and regulating medical device reprocessing is important. Such structures could include an infection control committee, multidisciplinary infection control team, and/or infection control nurse (Griffiths *et al.*, 2009). Committees or structures specific to medical devices reprocessing, for example a central sterilization committee, could prove even more beneficial in the context of Nepal where a more focussed effort will be necessary for the improvement of medical device reprocessing. Healthcare workers participating in the survey emphasised the need for regular supervision and monitoring for improving medical device reprocessing in the hospitals.

9.6.3 Infrastructure

Spaces allocated by the hospitals in Nepal for reprocessing of medical devices were not adequate for the effective execution of all processes of the reprocessing cycles. Indeed, about half of the hospitals did not have a specific area dedicated to the reprocessing of medical devices. Those hospitals which had a dedicated area for reprocessing did not have the basic requirements of an SSD with a clear unidirectional dirty to clean workflow. Not having a clear unidirectional workflow can compromise the sterility of medical devices after sterilization. Additionally, this can also place reprocessing staff at risk of acquiring an infection. Central SSDs (also known as CSSD) were not established in any of the hospitals.

This indicated that reprocessing activities were carried out in different areas of the hospital, for example, medical devices were disinfected, cleaned and wrapped at the point of use and then transported to the area where the sterilizer is located. Cleaning of medical devices at the point of use can increase the risk of transmission of pathogens to healthcare workers and patients. In addition, such practice is likely to adversely effect standardisation of the cleaning process within the hospital. This study found inconsistencies in methods used for cleaning medical devices within and across hospitals, for example, different combinations of disinfectant, detergent/soap and plain water were used for different percentages of reprocessing cycles (Section 7.2.2). Variation was also found in the methods of packaging cleaned medical devices (Section 7.2.4).

Clearly, all of the hospitals should allocate a central dedicated space or SSD for reprocessing of medical devices. Requirements for a dedicated space or the size of an SSD can vary depending on various factors, including hospital level, number of beds, the range of healthcare services provided, the range of surgical procedures carried out and patient load. A careful assessment needs to be carried out to establish the space requirements for the reprocessing of medical devices. The Guidelines for Health Institution Establishment, Operation and Upgradation Standards envision a CSSD with an area for receiving used medical devices, a cleaning room, a drying and packing area, a sterilization room, and a storage room for providing medical devices for inpatient services from a healthcare facility (Ministry of Health and Population - Government of Nepal, 2014b).

9.6.4 Development of human resources

Staff working in the hospitals had different levels of education ranging from a master's degree to no formal education and their healthcare responsibilities also varied. For reprocessing of medical devices, office assistants, who had very low education level or no formal education at all, were primarily involved in the reprocessing of medical devices. 50.1% (95% CI 33.1% - 67.1%) of the healthcare workers, including doctors, nurses, paramedics and office assistants, self-reported that they operated autoclaves by themselves sometimes. However, in real practice office assistants were solely involved in autoclaving for 97.0% (95% CI 87.5% - 99.3%) of the reprocessing cycles. Similarly, for 98.4% (95% CI 88.3% - 99.8%) of the reprocessing cycles, office assistants were involved in the cleaning of

medical devices. These findings indicated the rare involvement of higher level healthcare staff in reprocessing activities. Reprocessing of medical devices includes a number specialized scientific processes requiring specific knowledge and skills in a number of specialized areas (Section 2.5). In this study, the office assistants (compared with the nurses) were found to be statistically significantly less likely to have correct knowledge about the adequate steam sterilization temperature, glutaraldehyde sterilization, and the effectiveness of steam sterilization.

Indeed, in New Zealand, staff involved in the sterilization of medical devices are required to have certification in sterilizing technology. For the completion of the level 3 certification in sterilization technology, at least 400 hours of study are required. This study includes a number of courses in the area of microbiology, infection control, decontamination of medical devices, packaging of medical devices, different sterilization techniques, sterilization monitoring, and handling and storage of medical devices (New Zealand Sterile Sciences Association, 2017). On the other hand, in Nepal, information about decontamination and reprocessing of medical devices is included in a three-day "Infection Control and Healthcare Waste Management Training" program designed for district hospitals and smaller healthcare facilities; sections on cleaning, disinfection and sterilization are included in the training program. A time period of three hours is allocated for providing information on medical device reprocessing to the healthcare workers. Though the training program is intended for all categories of healthcare staff, and 51.6% (95% CI 42.0% - 61.0%) of the healthcare workers working in the hospitals included in this study reported prior training in infection control/prevention, its effectiveness in improving knowledge and skills of all categories staff including illiterate staff is unclear.

Designing and implementing a robust certification program in Nepal will only be possible after ensuring the provision of sterilization staff with a minimum educational qualification, and having all the required structures, policies and guidelines (both national and local) in place. To ensure the provision of certified sterilization staff, existing healthcare workers such as nurses and paramedics could be enrolled in the certification program and permitted to work as the sterilization staff in the hospitals. An alternative way to meet the need for qualified sterilization staff could be by hiring staff with a minimum required education qualification (such as higher secondary level) and then enrolling them in the certification program. It would be unreasonable to enrol office assistants with very low education levels or

no formal education in the certification programs and to give them the complete responsibility for reprocessing medical devices in the hospitals. However, their role in some aspects of medical devices reprocessing could be inevitable in the context of Nepal. Special training programs for them need to be developed and implemented. Their roles and responsibilities in medical device reprocessing need to be clearly specified and their performance needs to be closely monitored and supervised.

Cooperation and support from all categories of healthcare workers is important for effective reprocessing and reuse of medical devices. Healthcare workers need to have basic knowledge about different techniques and processes of medical device reprocessing for their supportive role in this area. The survey conducted among healthcare workers including doctors, paramedics, nurses and office assistants indicated that improvement is needed in their knowledge and attitudes about the sterilization and reuse of medical devices (sections 8.2 and 8.3). Doctors and paramedics were statistically significantly less likely to give correct answers to some of the knowledge questions compared with nurses (sections 8.2.3 and 8.2.4). Similarly, they were statistically significantly less likely to have a positive attitude towards a number of issues related to sterilization and reuse of medical devices (Section 8.3). These findings indicate that there is a need for educating all categories of healthcare workers on decontamination and reprocessing issues, with more focussed attention on paramedics and doctors. For the healthcare workers who are not directly involved in core processes of medical device reprocessing (i.e. cleaning, drying, inspection, packaging, sterilization and storage), a basic training program could be developed and used. The existing three-day training program could also serve this purpose but, the training program should also include information about the transmission of blood borne pathogens such as HIV, and emphasize the importance of standard practices or universal precautions to prevent their transmission. Similarly, basic knowledge about prions and their transmission should also be included in such training programs. Studies have demonstrated that training programs are effective in improving the knowledge of healthcare workers about infection control issues (Erkan *et al.*, 2011; Gurung, 2009; Huang & Wu, 2008). However, retention of knowledge for a long period of time (e.g. 2 years) after training has been reported to be poor (Calabro *et al.*, 2000). Therefore, frequent refresher training is indicated in the area of infection control. Healthcare workers participating in the survey predominantly pointed out the need for adequate training of concerned staff on sterilization and disinfection of medical devices in the hospitals.

9.6.5 Equipment

This study found a statistically significant association between equipment (i.e. autoclave type) and sterilization failure rate (Section 6.6). The study also found that the primary care hospitals (district level hospitals and district hospitals) in Nepal were relying on the very basic type of autoclaves for sterilization of medical devices; the autoclaves used were simple manually-operated large pressure-cookers with no precise mechanism for the displacement of air with steam. There were no practices of routine maintenance, periodic validation of performance and trouble-shooting of these autoclaves. The importance of such practices is greater when using these types of less effective autoclaves.

Currently, sophisticated autoclaves with pre-vacuum systems and other modern features (such as a fully automated operation) are available on the global market (Perkins, 1956; Thomas, 2009). These autoclaves are appropriate for sterilizing medical devices with narrow channels and lumens, and wrapped medical devices. The autoclave type was statistically significantly associated with sterilization failure in the hospitals in Nepal. Therefore, replacement of the basic autoclaves with modern autoclaves could significantly reduce the sterilization failure rates. There would be a cost implication of replacing existing autoclaves with the new ones. However, replacement of the existing autoclaves with more efficient autoclaves would be cost saving in the long term because of the ultimate reduction in the number of HAIs. However, purchasing a very expensive, fully-automated, high-end autoclave may not be ideal for small hospitals in a developing country because of the extreme budgetary limitations, lack of well-educated operators, increased complexity of the machine, poor water quality and increased risk of breakdown; this means that such a sophisticated autoclave may not be able to be run optimally. Therefore, it would be a wiser option to buy an improved manual autoclave with all the essential features for achieving the required level of sterility of medical devices (Huys, 2014).

Larger hospitals such as zonal hospitals need to give priority to replace their existing autoclaves with pre-vacuum autoclaves, because the range and the number of invasive/surgical procedures requiring reusable medical devices are likely to be greater in these hospitals; some of these procedures may require the use of medical devices with long narrow channels. An assessment of the volume of medical devices to be sterilized per day might prove useful in determining the size of the autoclave required. To ensure the reliability

of a new autoclave, it needs to be validated for its installation, operation and performance before initiating routine sterilization of medical devices using the new equipment.

It would be practically impossible for hospitals to avoid using the existing autoclaves for sterilizing reusable medical devices until they are replaced with more reliable autoclaves. Replacing the existing autoclaves with the new ones would take time and cost money which is not readily available. The existing autoclaves should be validated and operated strictly according to the manufacturer's instructions. Manufacturer's instruction manuals provide key guidance on the operation of equipment. Unfortunately, manufacturer's instruction manuals were not available for any of the autoclaves being used in the hospitals included in this study. Hospitals should make these manuals available to the staff responsible for operating the autoclaves. Use of such manuals requires staff to be highly literate. Specific staff need to be appointed for operating an autoclave in a hospital and they should be properly trained in autoclave operation. The sterilization process needs to be monitored strictly using relevant indicators (Section 4.2.1). These improvements in the operation of basic manual autoclaves can lead to great performance improvements (Huys, 1999).

9.6.6 Performance monitoring

Physical, chemical and biological indicators are used for monitoring the effectiveness of steam sterilization cycles; with biological indicators considered the gold standard (Section 4.2.1). Biological indictors were not being used for monitoring any of the steam sterilization cycles in the primary and the secondary care hospitals in Nepal. The only indicator used for monitoring the steam sterilization processes was autoclave tape (class 1 chemical indicator). Autoclave tape was used for 48.7% (95% CI 29.8% - 68.0%) of the steam sterilization cycles in the hospitals.

Irrespective of the use of different process indicators by the hospitals, this study independently tested 189 steam sterilization cycles in the hospitals with the autoclave tape, class 5 chemical indicator and the biological indicator. The results of the autoclave tape were not statistically significantly associated with the results of the biological ($p = 0.29$) and the class 5 chemical ($p = 0.27$) indicators. Practically, autoclave tape is affixed to the packages of medical devices before exposing them to a sterilization process. The use of autoclave tape is

not meant for determining the effectiveness of a steam sterilization cycle but it informs healthcare workers about the exposure of the medical device packages to a sterilization process by a change in its colour (Section 4.2.1). Also, the findings of this study clearly indicate that the autoclave tape does not equate to sterility of medical devices and hence, it cannot be used for monitoring the effectiveness of steam sterilization in the primary and the secondary care hospitals in Nepal.

Medical devices were being reused in the hospitals in Nepal without concrete evidence for the effectiveness of the steam sterilization process used. In addition, the high failure rate of the steam sterilization cycles found by this study showed that medical devices were being reused without effective sterilization. To stop the reuse of medical devices without concrete evidence of effective sterilization, use of a reliable and affordable process indicator is crucial. According to the findings of this study, the results of class 5 chemical indicators and the biological indicators were statistically significantly associated in the hospitals in Nepal ($p < 0.001$). The class 5 chemical indicators are relatively cheaper than the biological indicators (Section 6.7.2). The results of class 5 chemical indicators are easy to interpret and can be obtained immediately after sterilization. Immediate availability of the results of the indicator can help with releasing the sterilized packages for immediate use. Based on the characteristics of different process indicators and the findings of this study, it is recommended that hospitals should use a reliable chemical indicator, such as a class 5 chemical indicator, to monitor the effectiveness of each steam sterilization cycle, and the medical devices should be released for reuse only if the indicator shows an 'accept' result. As only the biological indicators can provide ultimate evidence of the effectiveness of a sterilization process, it is also recommended to use a biological indicator at a regular time interval, such as once per week, to ensure the effectiveness of the sterilization processes in a hospital. If a failed result is obtained with a class 5 chemical or a biological indicator, investigations should be carried out to identify the causes of such failures, and corrective actions need to be taken as soon as possible.

9.6.7 Documentation and record keeping

Documentation is one of the requirements of a quality management system (Australian Standard & New Zealand Standard, 2008). Documentation is crucial in medical device

reprocessing for various reasons. Hospitals should have a system to identify and trace medical devices used on patients so that the patients exposed to inadequately sterilized medical devices can be identified when needed. Record keeping is important also for the continuous quality improvement in medical device reprocessing. The practices of recording load number, the name of the operator, date and time, temperature/pressure and holding period were non-existent in all of the hospitals included in this study (Section 7.2.5). Such records can help in achieving the required temperature and time and in preventing failure of a steam sterilization cycle. There were no records of incidents and maintenance activities. Though autoclave tape was used in 48.7% (95% CI 29.8% - 68.0%) of the reprocessing cycles, the results were not recorded. Such non-existence of recording could have been because of the absence of any requirements for reporting such information to the hospital management and higher authorities, and also because many of the operators were illiterate. Mechanisms for recording, reviewing and reporting this information needs to be developed both at the hospital and the national level. Reporting of such information can be integrated into the national Health Management Information System (HMIS).

9.6.8 Water quality

The role of water in medical device reprocessing has already been discussed in Section 7.5.10. The role of water in medical device reprocessing is crucial in the cleaning of used medical devices and in the generation of steam for sterilizing medical devices. Additionally, the quality of water may also have an impact on the performance of the sterilizer. The pH of water used for reprocessing of medical devices in the hospitals in Nepal fell within an acceptable range (i.e. pH 6.0 to 9.0). However, many of the hospitals were using hard water (i.e. >150 mg /L $CaCO_3$) for reprocessing activities, including cleaning and steam generation. Hard waters require softening to make them suitable for cleaning used medical devices. Ideally, only treated (i.e. softened, purified and degassed) water is recommended for generation of steam for sterilization. Installing a water treatment plant in larger hospitals, such as zonal hospitals, for the purpose of medical device reprocessing is a good option. For smaller hospitals, water filtration might be an affordable solution.

9.7 Alternative Decontamination Techniques

Steam sterilization was the key sterilization technique used in the primary and the secondary care public hospitals in Nepal. Other decontamination techniques such as chemical sterilization/disinfection, steaming and boiling were also found to be used occasionally in a normal situation. However, such techniques were likely to be used more commonly during adverse conditions such as natural disasters. Low temperature sterilization techniques such as ethylene oxide sterilization and irradiation were non-existent. The focus of this study was steam sterilization of medical devices. However, some issues related to other decontamination techniques were also brought forward by this study.

Glutaraldehyde was found to be used by 23.0% of the hospitals to sterilize some medical devices including sharps. However, as discussed in Section 8.4.2.3, there was an ambiguity among healthcare workers about the exposure period while sterilizing medical devices using 2% glutaraldehyde solution. Clear instructions should be provided to the healthcare workers on the use of glutaraldehyde solution for decontaminating medical devices. A number of health hazards including irritation of sensory organs, skin sensitization, respiratory organ sensitization, chronic bronchitis and nasal symptoms have been reported to be associated with the use of glutaraldehyde solution in healthcare facilities (Takigawa & Endo, 2006). Healthcare workers should be made aware of such health hazards associated with the use of glutaraldehyde solution, and the routine practice of using appropriate PPEs including mask, goggles, gloves and apron while handing glutaraldehyde solution should be encouraged.

Other chemical formulations, which could be alternatives to the glutaraldehyde solution, are also available commercially and recommended by some guidelines. Such alternatives include ortho-phthalaldehyde, formaldehyde, peracetic acid, hydrogen peroxide, iodophors, phenolics, and chlorine-based compounds (Rutala *et al.*, 2008; WHO, 2016a). Chlorine-based compounds such as sodium hypochlorite and calcium hypochlorite were commonly used in the hospitals included in this study (Section 7.2.2). All of these chemical compounds have some advantages and disadvantages as disinfectants or sterilants (WHO, 2016a). Therefore, it is recommended that such advantages and disadvantages are carefully considered, and informed decisions made about the chemicals to be used. New formulations of chemical disinfectants frequently become available in the market. Such formulations need to be

considered for the purpose of decontamination of medical devices after a careful review and assessment in terms of their effectiveness, availability, affordability and safety.

Use of alternative decontamination techniques is unavoidable in some hospitals because some heat labile reusable medical devices such as flexible endoscopes cannot be reprocessed using heat and should be reprocessed with low-temperature decontamination techniques such as chemical sterilization. However, there is a rising concern about cross-resistance of microorganisms to biocides such as disinfectants and antibiotics i.e. microorganisms resistant to some disinfectants may also become resistant to antibiotics (Russell, 2003); this is because of molecular similarities between some disinfectants and some antibiotics and also because of similarities in their modes of action and mechanisms of resistance (Khan, Beattie & Knapp, 2016; Poole, 2002; Russell, 2003). Therefore, unnecessary use of chemical disinfectants should be minimized in hospitals.

Considering alternative techniques, special decontamination of medical devices that might conceivably be contaminated with prions cannot be ignored (Section 8.4.2.7). However, none of the healthcare workers except one doctor mentioned a possible association between prion contamination of medical devices and neurosurgical procedures. Therefore, healthcare workers need to be educated about possible contamination of medical devices with prions. The need for prion decontamination should be assessed carefully before making any decisions about special reprocessing of medical devices; such assessment should include identifying risk groups and procedures that involve contact of medical devices with brain tissues (e.g. neurosurgeries). Rutala and Weber (2010) have made the following recommendations for prion decontamination a) sterilizing medical devices at 134°C for 18 minutes in a pre-vacuum autoclave, b) sterilizing medical devices at 132°C for 60 minutes in a gravity-displacement cycle, c) immersing medical devices in 1 M NaOH for 60 minutes and then transferring to a tray for autoclaving for 60 minutes at 121°C or 134°C, and d) immersing medical devices in 1 M NaOH for 60 minutes, heating in a gravity displacement autoclave for 30 minutes in the immersed condition and then rinsing and sterilization using routine processes. However, merely heating at temperatures such as 121°C and 134°C may not be sufficient to guarantee prion inactivation because prions begin to lose their infectivity due to conformational rearrangement only at 138 °C (Shaw, 2004). Therefore, immersing medical devices in 1 M NaOH for 60 minutes and then autoclaving for 60 minutes at 121°C

or 134°C could be a preferable option. Similar options for prion decontamination are recommended by the CDC (2015).

9.8 Reprocessing During Emergencies

The importance of alternative decontamination techniques increases during emergencies when regular reprocessing systems cannot function properly. Emergencies in the context of medical device reprocessing could be breakage of the existing sterilizer, power outages, the absence of a qualified autoclave operator, and natural calamities such as earthquakes and floods. There was a tendency among healthcare workers to use alternative techniques during such emergencies (Section 8.4.2.9). Use of alternative techniques in emergencies might be unavoidable. However, hospitals should make efforts to minimize risks of transmission of pathogens due to the use of alternative techniques. In this study, healthcare workers mentioned a number of methods which could be used for decontaminating medical devices while the regular autoclave is not functioning. However, many of the methods mentioned by them such as drying, boiling and flaming, were suboptimal. Hospitals should be well prepared so that reprocessing of medical devices will not be compromised during emergencies. Preparedness may include planning for power backup, ensuring availability of a spare sterilizer and supplies, and managing qualified substitute staff for operating the sterilizer. Chemical disinfection/sterilization techniques and HLD using steam may also need to be used during emergencies. Clear guidance should be provided to the healthcare workers about the alternative methods. Decontamination procedures for emergencies need to be included in national and local guiding documents.

9.9 Occupational Health and Safety Considerations

Reprocessing of medical devices comprises a number of activities which are likely to expose healthcare workers to pathogens. Such activities are handling, transportation and cleaning of contaminated medical devices. Healthcare workers involved in such activities are required to follow preventive measures to protect themselves from the pathogens and from the hazardous effects of the chemicals used in reprocessing. Such measures include using appropriate PPEs during reprocessing activities, and receiving appropriate vaccinations. This study found very poor compliance with the use of PPEs during cleaning of medical devices (Section 7.5.4.1).

The reasons behind such poor compliance are not known. Healthcare workers' perception of the risk of transmission of pathogens during reprocessing activities, unavailability of PPEs and lack of proper guidance and monitoring could have been associated with the poor compliance. For 98.4 % (95% CI 88.3% - 99.8%; SE 1.5%) of the reprocessing cycles, office assistants were involved in the cleaning of used medical devices. Because of their very poor level of education, office assistants are likely to have inadequate knowledge about pathogenic microorganisms and their mode and risk of transmission. Therefore, office assistants are also likely to have a poor perception of the risk of transmission of the microorganisms among healthcare workers. Reasonably, a poor perception of the risk of transmission of microorganisms could have contributed to the very poor compliance of office assistants regarding PPE use. Additionally, insufficient availability of PPEs could have also contributed to the poor compliance. Indeed, Ohara *et al.* (2013) reported insufficiencies of PPEs in public and private hospitals in Kathmandu, the capital city of Nepal.

The consequence of non-compliance with the use of PPEs could be devastating; healthcare workers may get exposed to different pathogenic organisms and may get infected with them. Shrestha and Bhattarai (2006) reported that 20.9% of support staff working in a tertiary care public hospital in Nepal had evidence of current or past HBV infection. The authors indicated that the involvement of the support staff in the cleaning of used medical devices could have been linked to the HBV infection. The authors did not report about the compliance of the support staff with the proper and consistent use of the PPEs. However, the authors reported that the HBV infection was associated with the lack of vaccination for HBV ($p < 0.05$). The authors further reported that only 27.9% of the support staff had a full course of HBV vaccination.

Other important occupational health and safety issues associated with the use of autoclaves for sterilizing medical devices are physical hazards such as pressure and temperature. It is not uncommon to get news across the globe about explosion of autoclaves and similar pressurised steam equipment; a number of explosions of autoclaves and consequent killings or injuries of people have been reported (American Industrial Hygiene Association, 2017; Atreya, Kanchan & Nepal, 2016; 2015; Occupational Safety and Health Branch, 2008; Rahman, 2014). Autoclaves used in the primary care public hospitals (district level and district hospitals) in Nepal are not structurally much different from domestic pressure-cookers. These autoclaves have comparatively fewer automation features compared with

modern autoclaves. If a faulty autoclave is connected to the power source and left unmonitored, the pressure inside the autoclave may increase uncontrollably and the autoclave may explode. Such situations may occur due to blockages in valves such as safety valves and steam release valves. During the field work for this study, anecdotal information was reported by the autoclave operators about past incidents of autoclave explosions in their hospitals. There is also the risk of exposure of the autoclave operators to steam, with high temperatures leading to steam burns. Exposure to the hot steam may occur while opening the lid of the autoclave before letting it cool down. In addition, if containers or bottles with liquids are autoclaved and immediately removed out of the autoclave, the liquids may boil out or the bottles may explode causing harm to the healthcare staff. While being heated, surfaces of autoclaves become very hot and may cause burns if touched with bare skin

To minimize the risk of infection related to the medical device reprocessing, only qualified and trained healthcare staff should be involved in medical device reprocessing activities including cleaning medical devices. The issue of training about medical device reprocessing has already been discussed in Section 9.6.4. Interventions to improve the compliance of the healthcare workers with the recommended practices for using PPEs need to be developed and implemented. Hospitals should ensure uninterrupted and adequate supply of PPEs. Hospitals should also ensure that all staff involved in medical device reprocessing receive a full course of vaccinations for different pathogenic microorganisms including HBV.

Adequate training of staff on autoclave operation also helps in the prevention of physical hazards associated with the autoclave. Periodic maintenance of the autoclaves is equally important to prevent such hazards. Acquisition of modern automated equipment by the hospitals may also minimize the risks of adverse outcomes; however, staff would need to be trained properly in the operation of new equipment. Recording and reporting of incidents related to the equipment are important to solve the problems immediately and prevent the undesired outcomes. Hospitals should provide clear written guidance to healthcare workers on the occupational health and safety issues related to the reprocessing of medical devices.

9.10 Strengths and Limitations of the Study

Strengths

The most important feature of this study is its comprehensiveness. This study obtained a detailed picture of moist heat sterilization of medical devices in the primary and secondary care hospitals in Nepal by gathering information about hospitals, staff, equipment, policies and guidelines, standard practices, effectiveness, and water quality. The results of the study were presented and discussed in light of the principles of quality management. This study is likely to be the first ever study of this kind because of its comprehensiveness. No other studies comprising all of these facets (mentioned above) of steam sterilization were found while searching for the relevant literature.

In addition to the answers to the key research questions, this study identified some very important issues such as reprocessing medical devices during emergencies and the likely association between inadequate sterilization and use of antibiotics. This study led to the development of a number of research tools for investigating steam sterilization practices in hospitals; these tools can be used for investigating sterilization and reuse of medical devices in similar healthcare facilities in other countries.

The sampling design used for this study is another strength. Stratified clustered random sampling was used to select the hospitals included in this study. Statistical parameters such as margin of error, intra-class correlation coefficient 'roh' and DEFF were considered in determining the sample size i.e. the number of hospitals included in the study and the number of autoclave cycles tested. The selected hospitals represented all the primary and the secondary care public hospitals in Nepal. A similar approach was used for determining the number of participants for the survey (sections 4.3 and 4.4). Repeated testing of autoclave cycles within a hospital increased the chance of detecting a smaller failure or success rate in a hospital. This study provides 95 % confidence intervals for steam sterilization failure proportions in the primary and the secondary care hospitals in Nepal. No such scientific sampling design was used and no confidence intervals were reported by the previous studies estimating the effectiveness of steam sterilization in other countries.

Another important feature of this study is independent testing of steam sterilization cycles by an external (to the hospitals included in the study) researcher (i.e. the author of this thesis). The researcher visited each hospital and conducted the tests, audits and survey in the hospitals. This eliminated possible bias which could have been introduced to the previous studies in which hospitals or staff were provided with the testing tools and requested to report the results back to the researcher. A high response rate in the survey (i.e. 93.6%) can also be considered as one of the strengths of this study.

Limitations

The findings of this study may not be directly generalized to tertiary care public hospitals (i.e. central hospitals) and private hospitals in Nepal as these hospitals were not included in the study. However, recommendations made as a result of this study can be useful for the improvement of medical device reprocessing in these hospitals as well. There are 8 central public hospitals and more than 300 private hospitals including community hospitals in Nepal (Central Bureau of Statistics - Government of Nepal, 2013). This study did not cover smaller public and private healthcare facilities such as primary healthcare centres, health centres, health posts, sub-health posts, private clinics (outpatient only), and private dental clinics.

This study measured the effectiveness of the most commonly used sterilization method in the hospitals (i.e. steam sterilization) only. The effectiveness of other less commonly used decontamination processes such as chemical disinfection or sterilization were not evaluated. Measurement of the pressures of the sterilization chamber was dependent on the pressure gauges fixed on the autoclaves. The accuracy of the readings of these pressure gauges could not be absolutely guaranteed as no information about the calibration of these gauges was available. No other sophisticated devices such as pressure data loggers were used for obtaining actual pressures or temperatures inside the packages of medical devices during steam sterilization.

In this study, biological and class 5 Chemical indicators were not kept inside actual packages of medical devices, rather they were packaged separately in the same way as the actual medical devices were packaged. This was done to ensure that the daily sterilization activities would not be hampered because of the study-related activities. The indicator package simulated actual packages of medical devices to an extent. However, it might not have

exactly simulated complexities inside an actual package of medical devices. The temperature inside an actual package of medical devices may not come up to the required level as quickly as the temperature within the autoclave chamber (Kirckof *et al.*, 2009). The results of the Biological and Chemical Indicators reported by this study need to be understood in this context. Indeed, the proportion of positive or reject results shown by the biological and class 5 chemical Indicators might have been even higher if the indicators had been placed inside actual packages of medical devices. In addition, the autoclave operators may have become more attentive, due to the presence of the researcher, to undertaking autoclave testing and hence, they could have operated the autoclave more carefully on the days when the researcher was present than on the usual days. Therefore, the presence of the researcher during the operation of the autoclave may have also affected the proportion of reject results shown by the biological and class 5 chemical indicators.

Though the hospitals included in this study were selected randomly, selection of healthcare workers for the survey was not random for practical reasons, for example, it was not possible to obtain a complete list of healthcare workers available in a hospital. Survey questionnaires were provided to as many healthcare workers as could be approached. This could have led to the enrolment of healthcare workers who were relatively more approachable.

This study investigated all processes of medical device reprocessing using steam sterilization. However, the study did not investigate the handling of medical devices by the healthcare workers, which could add an extra risk of contamination. Prevention of infections associated with the reusable medical devices will only be possible when adequately sterilized medical devices are aseptically handled and used by healthcare workers.

9.11 Conclusions and Recommendations

This section provides conclusions from this study. In addition, recommendations discussed in the previous chapters and in the previous sections of this chapter are summarized in this section. The recommendations are divided into two categories; national-level and hospital-level recommendations. Recommendations for future research are also made. However, the recommendations listed in this section are only key recommendations. Recommendations are discussed in detail in chapters 6, 7 and 8, and in the previous sections of this chapter.

9.11.1 Conclusions

This study provided an overall picture of reprocessing and reuse of medical devices in primary and secondary care public hospitals in Nepal. Medical devices were reused only after reprocessing, and moist-heat sterilization (autoclaving) was the most commonly used sterilization technique in these hospitals. More than 70.0% of the moist-heat sterilization processes carried out in these hospitals were ineffective in killing a population (1.3×10^6) of bacterial spores contained in a biological indicator. Autoclave type and maximum pressure achieved during the holding period were the immediate factors statistically significantly associated with ineffective sterilization.

Overall compliance of the hospitals with the recommended practices for reprocessing of medical devices was poor. On average, only about one-fourth of the recommended practices were followed by the hospitals. Hospitals were least compliant with the recommendations for the steam sterilization process compared with the recommendations for other processes of a reprocessing cycle. Lower level hospitals, such as district-level hospitals, were less compliant with the recommended practices compared with the higher level hospitals. Most of the hospitals were using 'hard' water for cleaning used medical devices.

In general, the majority of healthcare workers had correct knowledge about most areas of medical device reprocessing. However, comparatively smaller percentages of healthcare workers had proper knowledge about some topics, including glutaraldehyde sterilization, wet sterilized packages and prion decontamination. Overall, the attitudes of healthcare workers towards issues related to decontamination and reuse of medical devices were found to be positive. Compared with nurses, paramedics and office assistants were less likely to have correct knowledge or positive attitudes towards many of the medical device reprocessing issues.

Management and support processes required for ensuring effective sterilization of medical devices were scarce. Adequate guiding documents such as guidelines and standards were not available either at the national or the local level. Infrastructure and equipment were inadequate for achieving the required level of sterility of medical devices. Steering structures and mechanisms, for ensuring adequate sterilization and use of medical devices, did not exist

in the hospitals. Sterilization processes were not monitored for their effectiveness using reliable indicators.

9.11.2 Recommendations

Based on the findings of this study, the following national-level key recommendations are made for the improvement of medical device reprocessing and reuse in Nepal. National-level institutions such as the NHTC, Management Division - Department of Health Services, DDA, Council for Technical Education and Vocational Training (CTEVT), Nepal Health Professional Council (NHPC), Ministry of Health, and universities are currently responsible for implementing these recommendations. Nepal is on the verge of entering into a new political system (i.e. a new federal system from a unitary system). Some of the structures within the current system are likely to be removed or changed when the new system is fully implemented. These recommendations apply to the institutions with current and future responsibility for ensuring and maintaining the safe reprocessing and reuse of medical devices in Nepal.

1. Develop a firm legal basis for ensuring adequate reprocessing and reuse of medical devices in healthcare facilities by developing required legislation (i.e. Acts and regulations and/or directives) in this area.

2. Clarify the roles and responsibilities of different government institutions associated with the regulation of use of medical devices in healthcare facilities. Such clarity on the roles and responsibilities can be made in the legislation documents mentioned in recommendation 1.

3. Develop standards and guidance documents for reprocessing and reuse of medical devices in healthcare facilities. Such documents should be developed based on the existing global and/or regional guidelines and standards (such as guidelines developed by WHO) and should include guidance for reprocessing medical devices during emergencies and prion decontamination of medical devices.

4. Develop and conduct a certification and recertification program on medical device reprocessing for training and certifying staff to work in medical device reprocessing units or departments in the hospitals. The certification program should specify the minimum education qualification required for enrolment in the program.

5. Update the existing training documents (including reference manual) on infection control and healthcare waste management, to incorporate current recommendations made in international guidelines and standards. This training program can be useful for providing basic knowledge on medical device reprocessing to healthcare workers who are not directly involved in the medical device reprocessing.

6. Ensure provision of required financial and technical support to the hospitals in upgrading infrastructure and equipment for ensuring effective reprocessing and sterilization of medical devices.

7. Ensure regular supervision and continued independent monitoring of medical device reprocessing and sterilization carried out in the hospitals. Ensure regular validation and maintenance of sterilization equipment in the hospitals.

The following key hospital-level recommendations are made for improving medical device reprocessing and ensuring the effectiveness of steam sterilization in hospitals in Nepal, based on the findings of this study. Some of these recommendations can be implemented only after the development of national documents which provide adequate guidance on the specific issues.

8. Develop a hospital-specific procedure manual for reprocessing and reuse of medical devices.

9. Centralize medical device reprocessing activities in the hospitals. Have a central sterilization service unit or department with a dirty to clean workflow and separate areas for receiving dirty medical devices, cleaning, packaging, sterilization, cooling and storage.

10. Replace existing pressure-cooker type autoclaves with at least improved manual autoclaves with gravity-displacement feature. It is recommended that higher level hospitals, such as zonal hospitals, have pre-vacuum autoclaves.

11. Ensure preventive maintenance and periodic validation of sterilization equipment.

12. Designate staff with at least secondary school education for reprocessing and sterilization of medical devices and train or certify them on their duties and responsibilities.

13. Ensure strict adherence of the staff to the standard practices for medical device reprocessing. Form a committee (for example, an infection control committee) to be responsible for ensuring such adherence, through regular supervision and monitoring.

14. Ensure the achievement of minimum pressure/temperature required for steam sterilization of medical devices.

15. Use reliable chemical indicators (such as class 5 chemical indicators) to evaluate the effectiveness of each steam sterilization cycle. If the result of the chemical indicator is 'reject', re-sterilize medical device packages before use. Biological indicators should be used periodically to further ensure the effectiveness of the sterilization process.

16. Autoclave tape should be used to confirm the exposure of each package of medical devices to a sterilization process, but not for measuring the effectiveness of a sterilization process.

17. Avoid the use of reusable steel drums for packaging medical devices. If the use of drums with a sterilization process is unavoidable, it should be validated for its appropriateness with the sterilization process.

18. Promote the use of PPEs during the cleaning of medical devices, and discontinue pre-cleaning decontamination of medical devices with hypochlorite solution.

19. Educate all healthcare workers about medical device reprocessing and reuse. Paramedics and office assistants should be given additional attention to educate them on medical device reprocessing (Section 8.4.2.2). Any reprocessing activities in which office assistants are involved need to be closely monitored.

20. Ensure softening of hard water for medical device reprocessing activities.

The following recommendations are made for future research in the area of medical device reprocessing.

21. Medical device reprocessing, including steam sterilization, in other categories of healthcare facilities in Nepal should also be studied. Such healthcare facilities include tertiary care public hospitals, private hospitals, non-profit making hospitals and community level public healthcare facilities such as primary healthcare centres, health centres and health posts.

22. The following areas of medical device reprocessing need further investigation in Nepal
    - Effectiveness of current and alternative cleaning methods (in order to develop recommendations about appropriate cleaning methods)
    - Existing sterile barrier systems and the shelf-life of the sterilized packages (for making recommendations about appropriate barrier systems and the shelf life of the sterilized packages)
    - Reprocessing of semi-critical medical devices (Section 2.2) such as endoscopes

23. This study indicated that inadequate sterilization may lead to overuse of antibiotics in healthcare facilities. This issue needs to be further studied and explained, particularly given the risk of antibiotic-resistant organisms. This finding also suggests that studying the associations between inadequacies in other infection control measures and overuse of antibiotics is important.

24. Investigations of reprocessing of medical devices in other developing countries will help in making country-specific recommendations for improving medical device reprocessing, and decreasing the burden of HAIs in those countries.

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APPENDICES

APPENDIX 1: KNOWLEDGE AND ATTITUDE QUESTIONNAIRE

KNOWLEDGE AND ATTITUDE QUESTIONNAIRE ____/_____

ज्ञान तथा मनोवृत्ति प्रश्नावली

Sterilization and Reuse of Medical Devices

मेडिकल औजारहरुको निर्मलिकरण तथा पुन: प्रयोग

A. DEMOGRAPHIC INFORMATION

जनसांख्यिकीय जानकारी

Please check (√) in the box that corresponds to your answer.

आफ्नो उत्तर भएको कोठामा चिन्ह (√) लगाउनुहोस्।

1. Gender: ☐Male ☐Female ☐Other
   लिंग पुरुष महिला अन्य

2. Age (in years): _____
   उमेर (वर्षमा)

3. What is your highest level of medical or health education?
   तपाईंको सबभन्दा माथिल्लो तहको चिकित्सा वा स्वास्थ्य शिक्षा के हो?

   ☐PhD
   विध्यावारिधि

   ☐Masters (MD/MS or Equivalent)
   स्नातकोत्तर (एम.डि./एम.एस. वा सो सरह)

   ☐Masters (MN/MSc Nursing or Equivalent)
   स्नातकोत्तर (एम.एन./एम. एस्सी नर्सिङ वा सो सरह)

   ☐Bachelors (MBBS or Equivalent)
   स्नातक(एम. बि. बि. एस. वा सो सरह)

   ☐Bachelors (BN/BSc Nursing or Equivalent)
   स्नातक(बि.एन. /बि. एस्सी. वा सो सरह)

   ☐Certificate (Health Assistant/HA)
   प्रमाणपत्र तह (स्वास्थ्य सहायक / एच ए)

   ☐Certificate (Staff Nurse)
   प्रमाणपत्र तह (स्टाफ नर्स)

   ☐Auxiliary Health Worker (AHW)
   सहायक स्वास्थ्य कार्यकर्ता (अ.हे.व.)

   ☐Auxiliary Nurse Midwife (ANM)
   अ.न.मि.

   ☐ Other (please specify) _____
   अन्य (कृपया उल्लेख गर्नुहोस्)

4. Your Job Title: _____
   तपाईंको पद

5. For how long have you been working as a healthcare worker? _____ years
   तपाईंले स्वास्थ्य कार्यकर्ताको रुपमा काम गर्नु भएको कति बर्ष भयो? वर्ष

6. Your current employment status is ☐Permanent ☐Contract /Temporary
   तपाईंको हालको जागिरको स्थिति स्थायी करार/अस्थायी

B. KNOWLEDGE

ज्ञान

1. Have you ever received training on
   के तपाईंले कहिल्यै निम्न लिखित बिषयमा तालिम लिनु भएको छ?

   a) Infection Control /Prevention ☐Yes ☐No
      संक्रमण नियन्त्रण /रोकथाम छ छैन

   b) Sterilization and Disinfection ☐Yes ☐No
      निर्मलिकरण तथा संक्रमण निवारण छ छैन

   c) Operation of Autoclaves ☐Yes ☐No
      अटोक्लेभको सन्चालन छ छैन

To answer the following questions, please circle the number on the scale to show how you agree with the statement.

निम्न प्रश्नहरुको उत्तरदिन उल्लेख गरिएका भनाइहरुसँग कत्तिको सहमत वा असहमत हुनुहुन्छ सो अनुसार दिईएको स्केलमा भएका अंकहरु मध्ये कुनै एकमा गोलो घेरा लगाउनुहोस्।

2. Used medical devices harbour a variety of microorganisms that could be transmitted among patients and healthcare workers.
   प्रयोग भैसकेका मेडिकल औजारहरुमा बिभिन्न किसिमका कीटाणुहरु पाइन्छन जुन बिरामि र स्वास्थ्य कार्यकर्ताहरुमा सर्न सक्छन्।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

3. Sterilization kills all microorganisms including spores.
   निर्मलीकरण गरेमा स्पोर लगायत सम्पुर्ण कीटाणुहरू मर्छन।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

4. Immersion of medical devices in 2 % glutaraldehyde for 10 minutes constitutes sterilization.
   मेडिकल औजारहरुलाइ २% ग्लुटरलडिहाइडमा डुबाएर १० मीनेट राख्नु भनेको निर्मलिकरण गर्नु हो।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

5. Autoclaving is not as effective as chemical methods for killing microorganisms.
   किटाणुहरू मार्नको लागि अटोक्लेभ गर्ने बिधि रासायनिक बिधि जत्तिको प्रभाबकारि हुँदैन ।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

6. Wet sterilized packs of medical devices obtained from autoclaving are considered to be contaminated.
   अटोक्लेभ गरिसकेपछि निकालिएका मेडिकल औजारका भिजेका पोकाहरुलाइ दूषित मान्नु पर्दछ।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

7. For autoclaves being used at your hospital, the temperature inside the autoclave chamber while sterilizing medical devices is
   तपाइको अस्पतालमा प्रयोग भैरहेको अटोक्लेभमा मेडिकल औजारहरुको नीर्मलिकरण भैरहँदा अटोक्लेभ भित्रको तापक्रम यसप्रकार हुन्छ

   _____°C डिग्री सेन्टिग्रेड

8. For how long should wrapped medical devices be kept at **this temperature** (mentioned in the answer to question 7) to sterilize them?
   पोको पारेर राखिएका मेडिकल औजारहरुलाइ नीर्मलिकरण गर्दा **उक्त तापक्रममा** (प्रश्न ७ को उत्तरमा उल्लेखित) कति लामो समय सम्म राखिनु पर्दछ?

   _____ minutes
   मीनेट

9. How long can we store wrapped sterilized medical devices at room temperature before using them?
   हामीले पोकोपारि निर्मलीकरण गरि राखेका मेडिकल औजारहरु प्रयोग गर्नुभन्दा अगाडी कोठाको तापक्रममा कति अबधि सम्म राख्न सक्छौं?

   _____ days
   दिन

10. Do you ever operate an autoclave? ☐Yes ☐No
    के तपाईं कहिल्यै अटोक्लेभ सञ्चालन गर्नु हुन्छ? गर्छु गर्दिन

11. Please check (√)the **single** highest level of decontamination process appropriate for the following medical devices
    तलका मेडिकल औजारहरुको लागि उपयुक्त सबैभन्दा माथिल्लो स्तरको एउटा दुषणनिवारण प्रकृयामा चिन्ह लगाउनुहोस्।

a)	Auroscope ear piece अरोस्कोपको कानमा प्रयोग गरिने भाग	☐*Cleaning* *सफाइ*	☐*Disinfection* *संक्रमण निवारण*	☐*Sterilization* *निर्मलीकरण*
b)	Ear syringe कानमा प्रयोग गरिने सिरिन्ज	☐*Cleaning* *सफाइ*	☐*Disinfection* *संक्रमण निवारण*	☐*Sterilization* *निर्मलीकरण*
c)	Metal forceps धातुको चिम्टि	☐*Cleaning* *सफाइ*	☐*Disinfection* *संक्रमण निवारण*	☐*Sterilization* *निर्मलीकरण*
d)	Scalpel handle स्काल्पलको बिंड	☐*Cleaning* *सफाइ*	☐*Disinfection* *संक्रमण निवारण*	☐*Sterilization* *निर्मलीकरण*

e) Thermometer ☐*Cleaning* ☐*Disinfection* ☐*Sterilization*
थर्मोमिटर *सफाइ* *संक्रमण निवारण* *निर्मलीकरण*

f) Vaginal speculum ☐*Cleaning* ☐*Disinfection* ☐*Sterilization*
योनि जांचको लागि प्रयोग गरिने स्पेकुलम *सफाइ* *संक्रमण निवारण* *निर्मलीकरण*

12. Do patients visiting this hospital ever show concern about sterility of medical devices?
के यस अस्पतालमा आउने बिरामिहरुले मेडिकल औजारहरुको निर्मलिकरणको अवस्थाको बारेमा कहिल्यै चासो देखाउंछन्?

☐Yes ☐No
देखाउंछन् देखाउंदैनन्

13. In your opinion, how can sterilization and reuse of medical devices be improved in your hospital?
तपाईंको बिचारमा तपाइको अस्पतालमा प्रयोग हुने मेडिकल औजारहरुको नीर्मलिकरण तथा पुन: प्रयोग कसरि सुधार गर्न सकिन्छ?

_____
_____
_____

14. If something goes wrong with the autoclave in your hospital, what do you do until the autoclave is repaired or replaced with a new one?
यदि तपाईंको अस्पतालको अटोक्लेभ बिग्रियो भने त्यो अटोक्लेभ नबनाइन्जेल वा नयाँ नफेरुन्जेल के गर्नु हुन्छ ?

_____
_____
_____

15. Do we need to change the routine sterilization process for medical devices for neurosurgical procedures?
के हामिले स्नायु सम्बन्धि सल्यक्रिया गर्दा मेडिकल औजारहरुको नियमित निर्मलिकरण प्रकृयामा परिवर्तन ल्याउनु आबस्यक छ ?

☐Yes ☐No
छ छैन

If yes, why?
यदि छ भने किन छ? _____

C. ATTITUDE

मनोवृत्ति

To answer the following questions, please circle the number on the scale to show how you agree with the statement.

निम्न प्रश्नहरुको उत्तरदिन उल्लेख गरिएका भनाइहरुसँग कत्तिको सहमत वा असहमत हुनुहुन्छ सो अनुसार दिईएको स्केलमा भएका अंकहरु मध्ये कुनै एकमा गोलो घेरा लगाउनुहोस्।

1. Reuse of medical devices is an important patient safety issue.
   मेडिकल औजारहरुको पुन:प्रगोग बिरामिको शुरक्षा को सन्दर्भमा एउटा महत्वपूर्ण् बिषय हो।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

2. Decontamination of medical devices reduces the risk of infection in patients and healthcare workers.
   मेडिकल औजारहरुको दुषणनिवारणले बिरामी र स्वास्थ्य कार्यकर्ताहरुमा संक्रमणको खतरा घटाउँछ।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

3. Written policies and standards are not necessary for ensuring appropriate decontamination of medical devices.
   मेडिकल औजारहरुको उपयुक्त दुषणानिवारण सुनिश्चित गर्न लिखित निति तथा मापदण्डहरु आवश्यक पर्दैनन्।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

4. Availability of sterilizers and supplies supports routine decontamination of medical devices.
   निर्मलिकरण गर्ने साधन र सामग्रीहरु उपलब्ध भएमा मेडिकल औजारहरुको नियमित दुषणानिवारणमा सहयोग पुग्दछ।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

5. Monitoring of the sterilization process does not deserve the same attention to detail applied to other key patient care activities.
   बिरामीलाइ दिइने अन्य मुख्य सेवाहरुमा जत्तिकै विस्तृत रुपमा निर्मलिकरण प्रकृयाको अनुगमनमा ध्यान दिनु आवश्यक छैन।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

6. Training on the operation of sterilizer/autoclave helps ensure adequate sterilization of medical devices.
   अटोक्लेभ सन्चालन सम्बन्धि तालिमले मेडिकल औजारहरुको पर्याप्त निर्मलिकरण शुनिश्चित गर्न सहयोग गर्छ।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

7. Cleaning before sterilization is an unnecessary process.
   मेडिकल औजारहरुलाइ निर्मलिकरण गर्नु अघि सफा गर्ने काम अनावस्यक छ ।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

8. If an instrument is not soiled visibly, we do not need to clean it before sterilization.
   यदि कुनै उपकरण आंखाले देखिनेगरि फोहोर भएको छैन भने त्यसलाइ निर्मलिकरण गर्नु अघि सफा गरिरहनु पर्दैन ।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

9. I would feel safe being treated as a patient using medical devices sterilized in this hospital.
   यस अस्पतालमा निर्मलिकरण गरिएका मेडिकल औजारहरु प्रयोग गरि बिरामिको रुपमा मेरो उपचार हुंदा म शुरक्षित महसुस गर्दछु।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

10. The number of staff involved in decontamination of medical devices in this hospital is not adequate.
    यस अस्पतालमा दुषणनिवारण कार्यमा संलग्न हुने कर्मचारिहरुको संख्या पर्याप्त छैन।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

11. Every patient attending healthcare facilities must be considered potentially HIV positive.
स्वास्थ संस्थामा आउने हरेक बिरामीलाई सम्भावित एच आई भि पोजिटिभ ब्यक्तिको रुपमा हेरिनु पर्दछ।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

12. Deviation from routine reprocessing procedures for medical devices is required when the devices had been used in patients with HIV.
यदि मेडिकल औजारहरु एच आइ भि पोजिटिभ बिरामिहरुमा प्रयोग गरिएका छन भने त्यस्ता औजारहरुको पुन:प्रसोधन सधै गरिने भन्दा फरक किसिमले गर्नु पर्दछ ।

1	2	3	4	5	6	7
Strongly Disagree पुरै असहमत छु			Neither Agree or Disagree सहमत वा असहमत दुवै छैन			Strongly Agree पुरै सहमत छु

APPENDIX 2: AUDIT TOOL FOR MOIST HEAT STERILIZATION PRACTICES

Hospital No: _____ **Date: _ _/_ _/_ _ _ _** **Observation No: ___/___**

AA. GENERAL

S.No.	Check Points	Yes	No	NA	Comments
AA1	Decontamination activities take place in a dirty to clean workflow				
AA2	Single-use items are reprocessed				

AA3. Design of the reprocessed medical devices

☐Solid, hollow ☐Pin and box joints ☐Lumen, tubing, tortuous paths

☐Porous ☐Other (specify_____)

AA4. Material of the reprocessed medical devices

☐Metal ☐Non-metal

AB. TRANSPORT

S.No.	Check Points	Yes	No	NA	Comments
AB1	Medical devices are transported to the decontamination area using a rigid, durable, leak-proof container that has a tight-fitting lid				
AB2	Container used for transporting medical devices is easy to clean and disinfect				

AC. CLEANING & DISINFECTION

AC1. Medical devices are cleaned before sterilization. ☐Yes ☐No

AC2. Time period between use and cleaning of medical devices _____ minutes

AC3. Used medical devices are soaked in or sprayed with water before cleaning to prevent drying.

☐Yes ☐No

AC3. Personnel involved in cleaning of medical devices

☐Doctors ☐Nurses ☐HA/AHW/ANM ☐Support staff

☐Other (Specify) _____

AC4. Cleaning methods used

☐Manual ☐Automated ☐Both ☐None

AC5. Specific procedures and solutions used for cleaning and disinfection of medical devices before sterilization

☐Water ☐Water and detergent/soap ☐Ultrasonic washers

☐Enzymatic cleaner ☐Disinfectant solution ☐Other (Specify)_____

S.No.	Check Points	Yes	No	NA	Comments
AC6	Cleaning is done in a separate area from where the instrument will be used (i.e., designated dirty area)				
AC7	Medical devices are pre-disinfected before cleaning (e.g. with hypochlorite solution)				
AC8	Following personal protective equipment are used during cleaning of used instruments				
	a) Eye protection				
	b) Gloves				
	c) Protective clothing				
	d) Facemask				
AC9	Medical devices are opened/dismantled for cleaning purpose				
AC10	Medical devices are submerged in water while washing them manually using a brush				
AC11	For instruments with lumens, all channels are cleaned using cleaning brushes of appropriate size				
AC12	Cleaning brushes are single use, disposable items				
AC13	After completion of cleaning process, reusable brushes are cleaned and either high level disinfected or sterilized				
AC14	Instruments are rinsed thoroughly with water after cleaning				
AC15	Medical devices are dried with low-linting (disposable or reusable) towels immediately after rinsing				
AC16	Enzymatic cleaner, detergent, and/or disinfectant are used according to manufacturer's instructions				
AC17	Enzymatic cleaner, detergent, and/or disinfectant are discarded according to manufacturer's instructions				

AD. INSPECTION

S.No.	Check Points	Yes	No	NA	Comments
AD1	All instruments are inspected every time after cleaning				
AD2	An illuminated magnifier is used to inspect instruments				

AE. PACKAGING

AE1. Sterile barrier system used

☐Single wrapped/pouch

☐Double wrapped in wrapping material or pouches, double wrapped container or tray, reusable sterilization container according to manufacturer's instructions

☐Combination of two or more systems, for example, a reusable sterilization container with an inner sterile barrier system

☐None

AE2. Wrapping material used

☐Paper

☐Cellulose/non-cellulose based non-woven wrapping materials

☐Cellulose/non-cellulose based woven wrapping materials

☐Linen

☐Other (specify_____)

AE3. Wrapping technique used

☐Envelope-fold wrapping technique

☐Square-fold wrapping technique

☐Other (specify_____)

S.No.	Check Points	Yes	No	NA	Comments
AE4	Hinged devices are open and devices are disassembled (if indicated by the manufacturer) while packaging them				
AE5	Packages to be sterilized are labelled with				
	a) The sterilizer used				
	b) The cycle or load number				
	c) The date of sterilization				
	d) The expiration date				

AF. STERILIZATION (AUTOCLAVING)

AF1. Personnel involved in sterilization of medical devices (autoclaving)

☐Doctors ☐Nurses ☐HA/AHW/ANM ☐Support staff

☐Other (Specify) _____

S.No.	Check Points	Yes	No	NA	Comments
AF2	Timer is used to monitor holding period of the autoclave cycle				
AF3	Holding period of the autoclave cycle starts when the pressure gauze shows the reading of required pressure (e.g.15 lbs)				
AF4	The following parameters are recorded for each sterilization cycle:				
	a) Cycle/load number				
	b) Operator				
	c) Date and Time				
	d) Pressure				
	e) Temperature and exposure time				
	f) Holding period				
AF5	Indicators used for monitoring sterilization process				
	a) Autoclave tape				
	b) Chemical Indicator				
	c) Biological Indicator				
AF6	Results for indicator recorded				
	a) Autoclave tape				
	b) Chemical Indicator				
	c) Biological Indicator				
AF7	Sterilizer physical parameters are reviewed after each run				
AF8	Indicator tape is used on the outside of each wrapped package				
AF9	Sterilized packs are intact and dry				

AG. TRANSPORT AND STORAGE

S.No.	Check Points	Yes	No	NA	Comments
AG1	Sterilized packages are checked for integrity and compromised packages are repackaged and re-sterilized before use				
AG2	Sterilized items are transported and delivered in a dry and clean container				
AG3	Sterilized packages are allowed to cool down to room temperature before storage				
AG4	Separate area is allocated for storage of sterilized medical devices				

AG5	Sterilized packages are stored and distributed according to "the first one to enter is the first one to leave"				
AG6	The area for storing sterilized packages is a well-ventilated area that provides protection against dust, moisture, insects, and temperature and humidity extremes				

APPENDIX 3: HOSPITAL SUMMARY INFORMATION SHEET

Hospital No. _____

HA. GENERAL

HA1. Type of Hospital

☐Zonal ☐District ☐District Level

HA2. Number of beds: _____

HA3. Number of staff currently working in the hospital

Doctors	Nurses	HA/AHW/ANM	Support staff	Others	**Total**

HA4. Available Clinical Services

☐Inpatient ☐Outpatient ☐Major surgeries ☐Minor surgeries

☐Specialized Services ☐Others (specify _____)

HB. REPROCESSING OF MEDICAL DEVICES

HB1. A separate area is designated for reprocessing of medical devices. ☐Yes ☐No

HB2. Hand washing facility is available in the medical devices reprocessing area. ☐Yes ☐No

HB3. Decontamination activities performed

☐Cleaning ☐Chemical disinfection ☐Boiling (in water)

☐Steaming ☐Dry heat ☐Moist heat under pressure (autoclaving)

☐Other methods (specify _____)

HB4. Available policies, guidelines and documentation on reprocessing of medical devices

☐Policies ☐Standards ☐Procedure manual ☐Flow charts

☐Training participant's manual ☐Employee training records

☐Other (specify_____)

HB5. Number of autoclaves in operation in the hospital _____

HB6. Information specific to the autoclaves in operation

S.N.	Information	Autoclave 1	Autoclave 2	Autoclave 3	Autoclave 4	Autoclave 5
a	Type					
b	Acquisition					
c	Installed by					
d	Validation					
e	Availability of spare seals, safety valves and pressure valves					
f	Presence of functioning heating system					
g	Date seal/gasket last changed					
h	Date safety valve last changed					
	Documents					
i	Manufacturer's manual					
j	Maintenance records					
k	Validation certificates					
l	Incident reports					
m	Other (specify)					

HB7. In total, for how long have you been without kerosene or other fuel/power for the sterilizer in the last week? _____

HB8. Budget plan for reprocessing of medical devices is available. ☐Yes ☐No

APPENDIX 4: TEST RESULTS FORM

Hospital No: _____ **Date: _ _/_ _/_ _ _ _** **Observation No: ___/___**

S.No.	Indicators	Results		Comments
PA 1	Autoclave Tape	☐Colour changed	☐ Colour not changed	_____
PA 2	Chemical Indicator (Class 5)	☐Accepted	☐Rejected	_____
PA3	Biological Indicator	☐Negative	☐ Positive	_____
	Water Testing			
PA4	pH	_____ (Water for cleaning)		
PA5	Hardness	_____(Water for Cleaning)		

PA6: Pressure Readings

Time (mins)	Pressure	Time (mins)	Pressure	Time (mins)	Pressure	Time (mins)	Pressure
1		19		37		55	
2		20		38		56	
3		21		39		57	
4		22		40		58	
5		23		41		59	
6		24		42		60	
7		25		43		61	
8		26		44		62	
9		27		45		63	
10		28		46		64	
11		29		47		65	
12		30		48		66	
13		31		49		67	
14		32		50		68	
15		33		51		69	
16		34		52		70	
17		35		53		71	
18		36		54		72	

APPENDIX 5: MANUFACTURER'S INSTRUCTIONS FOR PROPORE2 SELF-CONTAINED BIOLOGICAL INDICATOR

Instructions for Use

ProSpore2 Self-Contained Biological Indicator For steam/EtO sterilization cycles

Storage: 18-27°C, 30-70% relative humidity. Protect from freezing, sterilants, direct sunlight and all other forms of UV light. Do not refrigerate.
Exposure: Place one or more ProSpore2 Biological Indicators in a horizontal position in the most difficult location to sterilize. Run cycle.
Caution: After sterilization, the contents of the ampoule may be hot and under pressure. Failure to allow sufficient cooling time (10-15 minutes) may result in dangerous bursting of the ampoule. This is a single use product. Use of a unit in multiple cycles will invalidate the results and could potentially result in the release of non-sterile product.
Activation: Seal the cap immediately after retrieving the vials by pressing down firmly until flush with tube.
Allow the unit to cool (not longer than 15 minutes).
Crush the media ampoule with the tool provided or by squeezing the sides of the plastic tube.
Inspect the unit to ensure the spore carrier has been completely saturated with the growth media. If the spore carrier has not been completely saturated, simply hold the unit in a vertical position and gently tap the bottom on a hard surface until the carrier is immersed in the media.
Incubation*: Place the processed vial(s) and one unprocessed (control) vial in a vertical position in an incubator at:
• 55-60°C for steam (*Geobacillus stearothermophilus*) for 24 hours.
• 30-39°C for EtO (*Bacillus atrophaeus*) for 48 hours.
Monitoring: Examine the ProSpore2 vials daily during incubation. Record observations. All positive vials should be recorded and disposed of immediately. **DO NOT CONTINUE TO INCUBATE POSITIVE VIALS.** Continued growth may result in metabolism of amino acids in the absence of sugars, causing the pH to rise and a color reversion that is visibly darker than a sterile unit. These should be considered as positive for growth. Avoid misinterpretation by checking for growth daily and removing positives immediately.
Interpretation:
Control: The control vial should exhibit a color change to or toward yellow and/or turbidity. If the control ampoule does not show signs of growth, consider the test invalid.
Test: A failed sterilization cycle is indicated by turbidity and/or a color change to or toward yellow. A test ampoule that retains its original color indicates an adequate sterilization cycle.

*USP recommends incubating within 4 hours of removal from sterilizer.

IFU-PS2-A
Effective Date: 09-Sep-2015, Rev. 2

APPENDIX 6: MANUFACTURER'S INSTRUCTIONS FOR PROCHEM-SSW CLASS 5 CHEMICAL INDICATOR

ProChem SSW
Steam Sterilization Class 5 Integrator

250 / Bag Catalog Number: CI-SSW

Unprocessed

Processed Reject

Processed Accept

DIRECTIONS

1. Place a ProChem SSW Integrator in the center of each pack or load and process according to sterilizer manufacturer's directions.
2. Adequate sterilization conditions are reached when the dark bar has completely travelled through the reject window and has entered the accept window.
3. If the dark bar does not reach the accept window, reprocessing is required.
4. Indications for Use
   The integrating indicator is designed to chemically react over time with the critical parameters of steam sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles:
   Steam Sterilization Cycles:
   - 250°F/121°C, 30 minutes Gravity
   - 270°F/132°C, 4 minutes Dynamic Air Removal
   - 270°F /132°C, 15 minutes Gravity
   - 275°F/135°C, 3 minutes Dynamic Air Removal
   - 275°F/135°C, 10 minutes Gravity

   Steam Sterilization Cycles (IUSS):
   - 270°F/132°C, 4 minutes Dynamic Air Removal
   - 270°F/132°C, 3 minutes Gravity
   - 270°F/132°C, 10 minutes Gravity
   - 275°F/135°C, 3 minutes Dynamic Air Removal
   - 275°F/135°C, 3 minutes Gravity
   - 275°F/135°C, 10 minutes Gravity

APPENDIX 7: MANUFACTURER'S INSTRUCTIONS FOR AUTOCLAVE TAPE

MesaLabs

INSTRUCTIONS FOR USE

Autoclave Tape

1. Affix tape to item to be sterilized. Tape may be used to secure packages or solely as an external process indicator.
2. Sterilize items per in-house procedures.
3. Verify tape has changed color. Tape is intended to identify items having been exposed to a sterilization process.

Interpretation:

APPENDIX 8: CERTIFICATE OF ANALYSIS – PROSPORE 2 SELF-CONTAINED BILOGICAL INDICATORS

MesaLabs

CERTIFICATE OF ANALYSIS

MESA BIOLOGICAL INDICATORS

ProSpore2 Self-Contained Biological Indicators (with *Geobacillus stearothermophilus*) - Recommended for use in evaluating 121 C **steam** sterilization processes.

This document certifies that the biological indicators for this lot meet 'Mesa Labs' quality control specifications, AAMI/ISO 11138-1, AAMI/ISO 11138-3 and suggested performance parameters published in the current United States Pharmacopeia.

Thomas Halpenny
Quality Assurance Specialist
Mesa Labs

Manufacture: **08JAN2016**
Release: **26JAN2016**

Performance Data for Lot # **1266** Batch **1164S** Expiration Date **07/2017**

Organism: ***Geobacillus stearothermophilus*** ATCC No. 7953

Mean Disc Recovery	**1.3 x 10^6**	CFU* / 0.215" x 0.75" paper strip
D_{121} Value	**1.7**	minutes** (Saturated steam at 121.1°C)
D_{132} Value	**0.48**	minutes (Saturated steam, extrapolated from Z Value**)
Z Value	**18.9**	C*** approximate; (based on ISO 11138-3)

* colony forming units
** Determined on primary spore crop using Fraction-Negative (Spearman-Karber method) The D-value is reproducible only under the exact conditions under which it was determined. The user would not necessarily obtain the same results. Therefore, the user would need to determine the suitability for its particular use
*** See reverse side.

Resistance Characteristics: (Based on US Pharmacopeia Calculations)

AGENT	CONDITIONS	SURVIVED	KILLED
Saturated Steam	121.1 ± 0.5°C	**7.0** min.	**17.2** min.
Saturated Steam	132°C	**2.0** min.	**4.9** min.

Purity: No evidence of contaminants using standard plate count techniques.
Incubation: 24 hours at 55 - 60°C. See instructions for use.
Storage: 60 - 80°F (15-27°C), 30 - 70% RH, away from sterilizing agents, direct sunlight and all other forms of UV light. (Do Not Refrigerate).
Disposal: Do not use after expiration date. Sterilize all cultures before discarding.

09/17/12

Mesa Laboratories Inc. Omaha Manufacturing Facility 8607 Park Drive Omaha, NE 68127 USA
bi-support@mesalabs.com (303) 987-8000 FAX (402) 593-0921 www.mesalabs.com
Our Quality System is Registered to ISO 13485 Standards

APPENDIX 9: CERTIFICATE OF COMFORMANCE – PROCHEM SSW INTEGRATOR

MesaLabs

CERTIFICATE OF COMFORMANCE

Product(s) Name(s): MESA ProChem SSW Integrator

Catalog No.: 77-05-CI-SSW

Lot Number: 216 **Exp Date:** 02/2019

Product Description

Mesa ProChem SSW is a single use Class 5 integrating indicator.

Indications for Use

Mesa ProChem SSW is an integrating chemical indicator intended for monitoring the efficacy of steam sterilization cycles.

This is to certify that the product listed above has been tested by Mesa Labs, Omaha Manufacturing Facility, and satisfies performance requirements after exposure to dry saturated steam when tested under the conditions described in ANSI/AAMI/ISO 11140-1 for Class 5 process indicators.

This product is stable after exposure to steam and may be kept as a permanent record.

All products are manufactured following the US Food and Drug Administration Quality System Regulations, 21 CFR, Part 820.

Thomas Halpenny
Quality Assurance Specialist

27APR2016
Date

31May2013

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Our Quality System is Registered to ISO 13485 Standards

APPENDIX 10: MANUFACTURER'S INSTRUCTIONS FOR MEASURING HARDNESS OF WATER USING HI 96735C HARDNESS ISM

Dear Customer,
Thank you for choosing a Hanna product. This manual will provide you with the necessary information for the correct use of the instrument. Please read it carefully before using the meter. If you need additional technical information, do not hesitate to e-mail us at tech@hannainst.com.

Preliminary examination:

Please examine this product carefully. Make sure that the instrument is not damaged. If any damage occured during shipment, please notify your Dealer.

Each **HI 96735** Ion Selective Meter is supplied complete with:

- Two Sample Cuvettes and Caps
- 9V Battery
- Instruction Manual

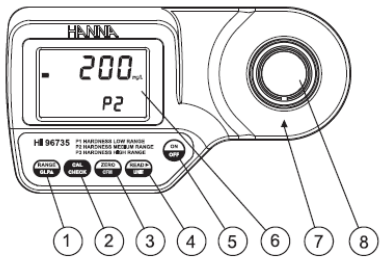
Note: Save all packing material until you are sure that the instrument works correctly. Any defective item must be returned in its original packing.

For more details about spare parts and accessories see "Accessories".

Technical specifications:

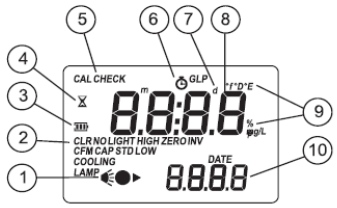
Range	LR 0 to 250 mg/L MR 200 to 500 mg/L HR 400 to 750 mg/L
Resolution	1 mg/L from 0 to 100 mg/L 5 mg/L from 100 to 750 mg/L
Accuracy	LR ±5mg/L ±4% of reading@ 25°C MR ±7 mg/L ±3% of reading@ 25°C HR ±10 mg/L ±2% of reading@ 25°C
Typical EMC Dev.	±5 mg/L
Light Source	Light Emitting Diode
Light Detector	Silicon Photocell with narow band interference filter @ 466 nm
Method	Adaptation of the EPA recommended method 130.1. The reaction between calcium, magnezium and the reagents causes a red-violet tint in the sample.
Environment	0 to 50°C (32 to 122°F); max 95% RH non-condensing
Battery Type	1 x 9 volt
Auto-Shut off	After 10' of non-use in measurement mode; after 1 hour of non-use in calibration mode; with last reading reminder.
Dimensions	192 x 104 x 69 mm (7.6 x 4.1 x 2.7")
Weight	360 g (12.7 oz.).

Functional description:



1. **RANGE/GLP/▲** key: press to change the range or press and hold for three seconds to enter *GLP mode*. In *calibration mode* press to edit the date and time.
2. **CAL CHECK** key: press to perform the validation of the meter, or press and hold for three seconds to enter *calibration mode*.
3. **ZERO/CFM** key: press to zero the meter prior to measurement, to confirm edited values or to confirm factory calibration restore. Press and hold for three seconds to start a preprogramed countdown prior to measurement.
4. **READ/▶/UNIT** key: In *measurement mode*, press to make a measurement, or press and hold for three seconds to change the measurement unit. In *GLP mode* press to view the next screen.
5. **ON/OFF** key: to turn the meter on and off.
6. Liquid Crystal Display (LCD)
7. Cuvette alignment indicator
8. Cuvette holder

DISPLAY ELEMENTS DESCRIPTION:

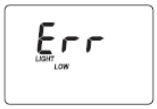


1. The measuring scheme (lamp, cuvette, detector), appears during different phases of zero or reading measurement
2. Error messages and warnings
3. The battery icon indicates the charge state of the battery
4. The hourglass appears when an internal check is in progress
5. Status messages
6. The chronometer appears when the reaction timer is running
7. The month, day and date icons appear when a date is displayed
8. Four digit main display
9. Measuring units
10. Four digit secondary display

Errors and warnings:

ON ZERO READING:

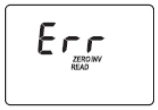
Light High: There is too much light to perform a measurement. Please check the preparation of the zero cuvette.



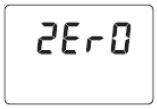
Light Low: There is not enough light to perform a measurement. Please check the preparation of the zero cuvette.

No Light: The instrument cannot adjust the light level. Please check that the sample does not contain any debris.

ON SAMPLE READING:



Inverted cuvettes: The sample and the zero cuvette are inverted.



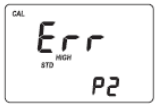
Zero: A zero reading was not taken. Follow the instructions of the measurement procedure for zeroing the meter.

Under range: A blinking "200" indicates that the sample absorbs less light than the zero reference. Check the procedure and make sure you use the same cuvette for reference (zero) and measurement.

Over Range: A flashing value of the maximum concentration indicates an over range condition. The concentration of the sample is beyond the programmed range: dilute the sample and re-run the test.

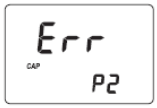
DURING CALIBRATION PROCEDURE:

Standard Low: The standard reading is less than expected.

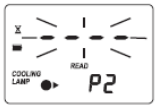


Standard High: The standard reading is higher than expected.

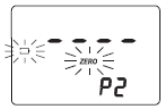
OTHER ERRORS AND WARNINGS:



Cap error: Appears when external light enters in the analysis cell. Assure that the cuvette cap is present.



Cooling lamp: The instrument waits for the lamp to cool down.



Battery low: The battery must be replaced soon.

Dead battery: This indicates that the battery is dead and must be replaced. Once this indication is displayed, normal operation of the instrument will be interrupted. Change the battery and restart the meter.

Measurement procedure:

1• Turn the meter on by pressing **ON/OFF**.

2• When the beeper sounds briefly and the LCD displays dashes and "P1" (Low range), "P2" (Medium range) or "P3" (High range), the meter is ready. The code that appears on the secondary display is the one of the last selected range. If necessary, press **RANGE/GLP/▲** to change range. The blinking "ZERO" indicates that the instrument needs to be zeroed first.

3• Add 0.5 mL of unreacted sample to the cuvette. With the plastic dropper fill the cuvette up to the 10 mL mark adding **HI 93735A** indicator reagent appropriate to the selected range.

4• Add two drops of **HI 93735B** buffer reagent. Replace the cap and shake gently to mix.

5• Place the cuvette into the cuvette holder and ensure that the notch on the cap is positioned securely into the groove.

6• Press **ZERO/CFM** and the lamp, cuvette and detector icons will appear on the display, depending on the measurement phase.

7• After a few seconds the display will show "-0.0-". The meter is now zeroed and ready for measurement. Remove the cuvette.

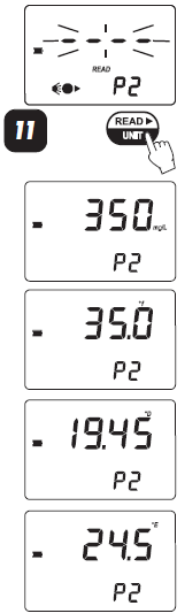
8• Add the content of 1 packet of **HI 93735C** fixing reagent. Replace the cap and shake gently to mix.

9• Replace the cuvette into the holder and ensure that the notch on the cap is positioned securely into the groove.

10• Press **READ/►/UNIT**. In all cases the lamp, cuvette and detector icons will appear on the display, depending on the measurement phase.

11 • At the end of measurement, the instrument directly displays the hardness in the last unit selected on the LCD. Press the **READ/►/UNIT** key repeatedly to change the reading unit: mg/L, °f, °C and °E respectively. The conversion factors are as follows:

1 mg/L = 0.1 °f = 0.0556 °D = 0.07 °E



INTERFERENCES:

Interference may be caused by excessive amounts of heavy metals.

Note: If the sample is very acidic, some extra drops of **HI 93735B** buffer reagent may be added.

Validation and Calibration procedures

Warning: do not validate or calibrate the instrument with standard solutions other than the Hanna **CAL CHECK™** Standards, otherwise erroneous results will be obtained.

For accurate validation and calibration results, please perform tests at room temperature (18 to 25°C; 64.5 to 77.0°F).

Use the Hanna CAL CHECK™ cuvettes (see "Accessories") to validate or calibrate instruments.

VALIDATION

Validation ▼

1 • Turn the meter on by pressing **ON/OFF**.

2 • When the beeper sounds briefly and the LCD displays dashes, the meter is ready.

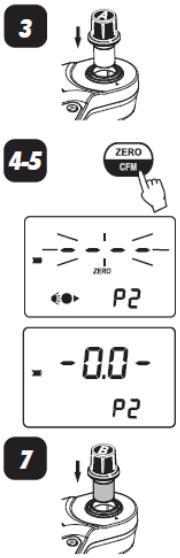
3 • Place the **CAL CHECK™ Standard HI 96735-11** Cuvette A into the holder and ensure that the notch on the cap is positioned securely into the groove.

4 • Press **ZERO/CFM** and the lamp, cuvette and detector icons will appear on the display, depending on the measurement phase.

5 • After a few seconds the display will show "-0.0-". The meter is now zeroed and ready for validation.

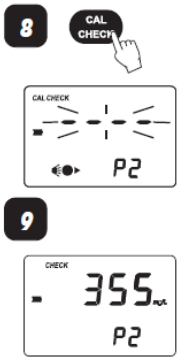
6 • Remove the cuvette.

7 • Place the **CAL CHECK™ Standard HI 96735-11** Cuvette B into the holder and ensure that the notch on the cap is positioned securely into the groove.



8 • Press **CAL CHECK** key and the lamp, cuvette and detector icons together with "CAL CHECK" will appear on the display, depending on the measurement phase.

9 • At the end of the measurement the display will show the validation standard value. The reading should be within specifications as reported on the **CAL CHECK™ Standard** Certificate. If the value is found out of specifications, please check that the cuvettes are free of fingerprints, oil or dirt and repeat validation. If results are still found out of specifications then recalibrate the instrument.



CALIBRATION

Calibration ▼

Note: It is possible to interrupt the calibration procedure at any time by pressing **CAL CHECK** or **ON/OFF** keys.

1 • Turn the meter on by pressing **ON/OFF**.

2 • When the beeper sounds briefly and the LCD displays dashes, the meter is ready.

3 • Press and hold **CAL CHECK** for three seconds to enter *calibration mode*. The display will show "CAL" during calibration procedure. The blinking "ZERO" asks for instrument zeroing.

4 • Place the **CAL CHECK™ Standard HI 96735-11** Cuvette A into the cuvette holder and ensure that the notch on the cap is positioned securely into the groove.

5 • Press **ZERO/CFM** and the lamp, cuvette and detector icons will appear on the display, depending on the measurement phase.

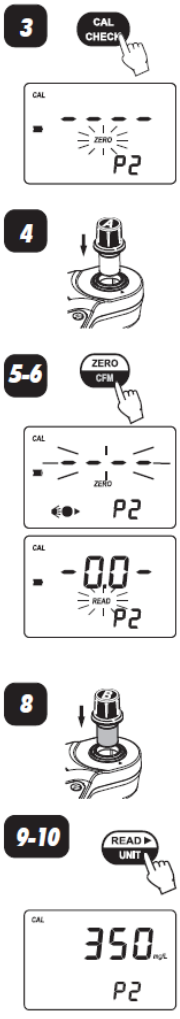
6 • After a few seconds the display will show "-0.0-". The meter is now zeroed and ready for calibration. The blinking "READ" asks for reading calibration standard.

7 • Remove the cuvette.

8 • Place the **CAL CHECK™ Standard HI 96735-11** Cuvette B into the holder and ensure that the notch on the cap is positioned securely into the groove.

9 • Press **READ/►/UNIT** and the lamp, cuvette and detector icons will appear on the display, depending on the measurement phase.

10 • The instrument will show for three seconds the **CAL CHECK™** standard value.



Note: If the display shows "STD HIGH", the standard value was too high. If the display shows "STD LOW", the standard value was too low. Verify that both **CAL CHECK™ Standard HI 96735-11** Cuvettes, A and B are free from fingerprints or dirt and that they are inserted correctly.

11 • Then the date of last calibration (e.g.: "01.08.2009") appears on the display, or "01.01.2009" if the factory calibration was selected before. In both cases the year number is blinking, ready for date input.

12 • Press RANGE/GLP/▲ to edit the desired year (2009-2099). If the key is kept pressed, the year number is automatically increased.

13 • When the correct year has been set, press ZERO/CFM or READ/▶/UNIT to confirm. Now the display will show the month blinking.

14 • Press RANGE/GLP/▲ to edit the desired month (01-12). If the key is kept pressed, the month number is automatically increased.

15 • When the correct month has been set, press ZERO/CFM or READ/▶/UNIT to confirm. Now the display will show the day blinking.

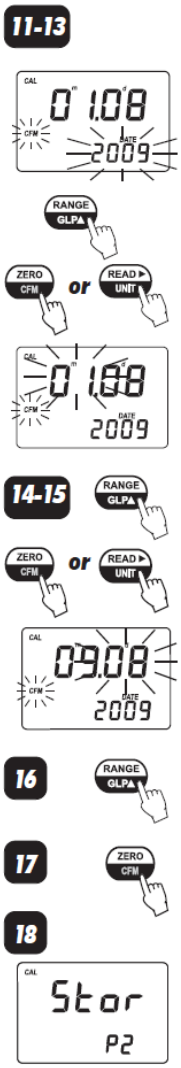
16 • Press RANGE/GLP/▲ to edit the desired day (01-31). If the key is kept pressed, the day number is automatically increased.

Note: It is possible to change the editing from day to year and to month by pressing READ/▶/UNIT.

17 • Press ZERO/CFM to save the calibration date.

18 • The instrument displays "Stor" for one second and the calibration is saved.

19 • The instrument will return automatically to *measurement mode* by displaying dashes on the LCD.



GLP

In *GLP mode*, the last calibration date can be verified and the factory calibration can be restored.

LAST CALIBRATION DATE

Last Calibration Date ▼

1 • Press and hold for three seconds RANGE/GLP/▲ to enter *GLP mode*. The calibration month and day will appear on the main display and the year on the secondary display.

2 • If no calibration was performed, the factory calibration message, "F.CAL" will appear on the main display and the instrument returns to *measurement mode* after three seconds.

FACTORY CALIBRATION RESTORE

Factory Calibration Restore ▼

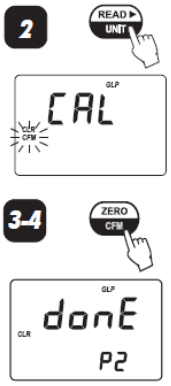
It is possible to delete the calibration and restore factory calibration.

1 • Press RANGE/GLP/▲ to enter *GLP mode*.

2 • Press READ/▶/UNIT to enter in the factory calibration restore screen. The instrument asks for confirmation of user calibration delete.

3 • Press ZERO/CFM to restore the factory calibration or press RANGE/GLP/▲ again to abort factory calibration restore.

4 • The instrument briefly indicates "donE" upon restoration of factory calibration prior returning to *measurement mode*.



Battery management

To save the battery, the instrument shuts down after 10 minutes of non-use in *measurement mode* and after 1 hour of non-use in *calibration mode*.

If a valid measurement was displayed before auto-shut off, the value is displayed when the instrument is switched on. The blinking "ZERO" means that a new zero has to be performed.

One fresh battery lasts for arround 750 measurements, depending on the light level.

The remaining battery capacity is evaluated at the instrument startup and after each measurement.

The instrument displays a battery indicator with three levels as follows:

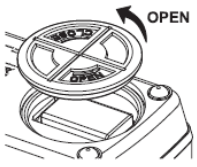
- 3 lines for 100 % capacity
- 2 lines for 66 % capacity
- 1 line for 33 % capacity
- Battery icon blinking if the capacity is under 10 %.

If the battery is empty and accurate measurements can't be taken any more, the instrument shows "dEAd bAtt" and turns off.

To restart the instrument, the battery must be replaced with a fresh one.

To replace the instrument's battery, follow the steps:

- Turn the instrument off by pressing ON/OFF.
- Turn the instrument upside down and remove the battery cover by turning it counterclockwise.



- Extract the battery from its location and replace it with a fresh one.
- Insert back the battery cover and turn it clockwise to close.

Accessories:

REAGENT SETS

HI 93735-00	Reagents for 100 tests (LR, 0 to 250 mg/L)
HI 93735-01	Reagents for 100 tests (MR, 200 to 500 mg/L)
HI 93735-02	Reagents for 100 tests (HR, 400 to 750 mg/L)
HI 93735-0	Reagents for 300 tests (LR - 100 tests, MR - 100 tests, HR - 100 tests)

OTHER ACCESSORIES

HI 96735-11	CAL CHECK™ Standard Cuvettes (1 set)
HI 721310	9V battery (10 pcs)
HI 731318	Cloth for wiping cuvettes (4 pcs)
HI 731331	Glass cuvettes (4 pcs)
HI 731335	Caps for cuvettes (4 pcs)
HI 93703-50	Cuvette cleaning solution (230 mL).

Warranty

HI 96735 is warranted for two years against defects in workmanship and materials when used for its intended purpose and maintained according to the instructions.

This warranty is limited to repair or replacement free of charge.

Damages due to accident, misuse, tampering or lack of prescribed maintenance are not covered.

If service is required, contact your dealer. If under warranty, report the model number, date of purchase, serial number and the nature of the failure. If the repair is not covered by the warranty, you will be notified of the charges incurred.

If the instrument is to be returned to Hanna Instruments, first obtain a Returned Goods Authorization Number from the Customer Service Department and then send it with shipment costs prepaid. When shipping any instrument, make sure it is properly packaged for complete protection.

To validate your warranty, fill out and return the enclosed warranty card within 14 days from the date of purchase.

Recommendations for Users

Before using these products, make sure that they are entirely suitable for your specific application and for the environment in which they are used.

Operation of these instruments may cause unacceptable interferences to other electronic equipment, this requiring the operator to take all necessary steps to correct interferences.

Any variation introduced by the user to the supplied equipment may degrade the instrument's EMC performance.

To avoid damages or burns, do not put the instrument in microwave oven. For yours and the instrument safety do not use or store the instrument in hazardous environments.

Hanna Instruments reserves the right to modify the design, construction or appearance of its products without advance notice.

For additional information, contact your dealer or the nearest

Hanna Customer Service Center.
To find the Hanna Office in your area, visit our web site

www.hannainst.com

IST96735 07/12

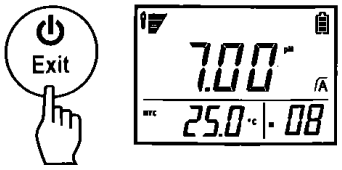
HANNA® instruments

APPENDIX 11: MANUFACTURER'S INSTRUCTIONS FOR MEASRING pH OF WATER USI NG METTLER TOLEDO FG2/EL2 pH METER

METTLER TOLEDO FG2/EL2
pH meter quick guide

English

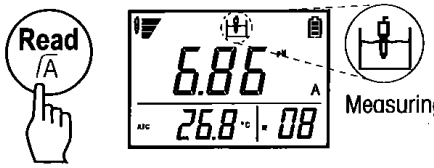
Switching the instrument on/off

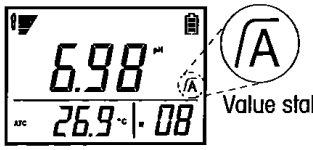


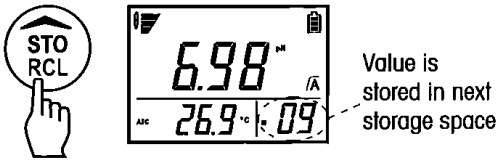
Hold button for 3 seconds, to switch instrument off.

Performing a measurement

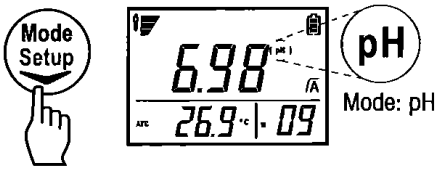
Insert electrode into sample

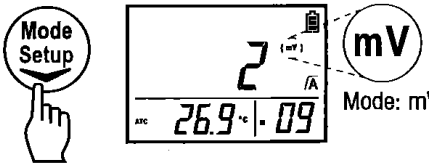




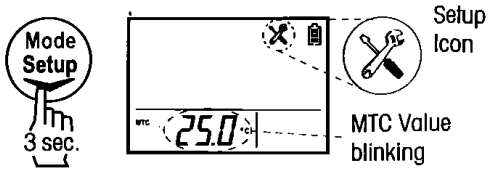


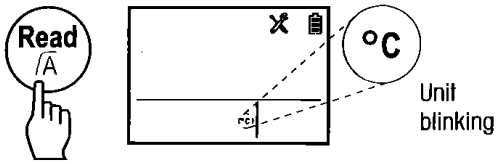
Changing the mode

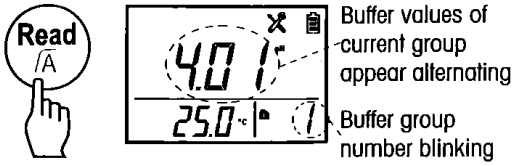


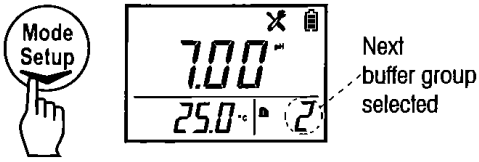


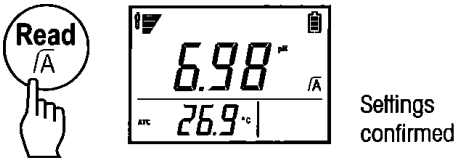
Entering calibration settings











▲▼	to change value / setting
Exit	to leave Setup
Read	to confirm setting

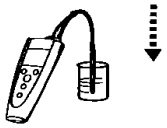
Predefined buffer groups:
(at 25°C)

B1	1.68	4.01	7.00	10.01	
B2	2.00	4.01	7.00	9.21	11.00
B3	1.68	4.00	6.86	9.18	12.46

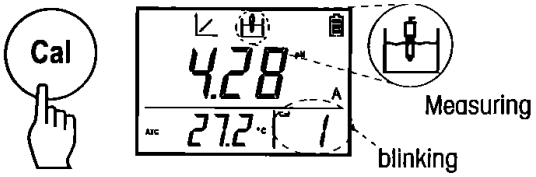
METTLER TOLEDO FG2/EL2 pH meter quick guide

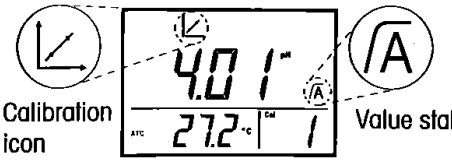
English

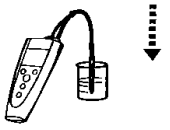
Performing a 2-point calibration



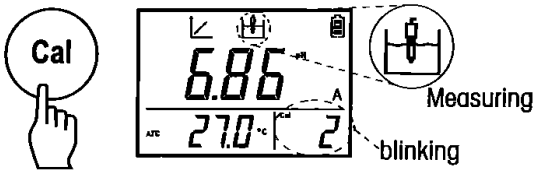
Insert electrode into first pH buffer

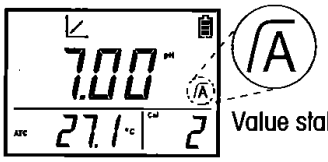


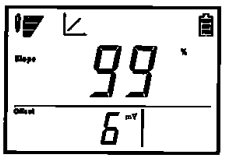




Insert electrode into second pH buffer

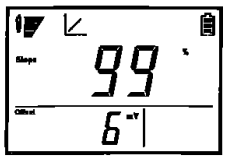






Calibration result is shown for 3 seconds

Recalling calibration data

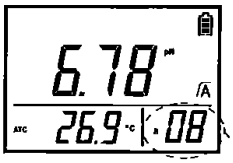


Last calibration result is shown for 3 seconds

Recalling measurement data

Last measurement result is shown

Last storage space

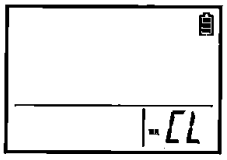


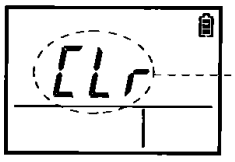
Use the arrow keys to scroll through results

Previous storage space

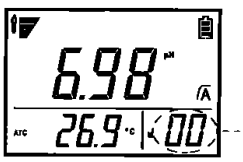
Clear memory

Scroll through all results, until "CL" is displayed instead of the storage place.





blinking



memory cleared

no results stored

Quick guide: FG2/EL2 pH meter

0702/10.52 ME-51710494

APPENDIX 12: UNIVERSITY OF CANTERBURY HUMAN ETHICS COMMITTEE APPROVAL LETTER

UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

HUMAN ETHICS COMMITTEE

Secretary, Lynda Griffioen
Email: human-ethics@canterbury.ac.nz

Ref: HEC 2015/139

14 December 2015

Gopal Panta
School of Health Sciences
UNIVERSITY OF CANTERBURY

Dear Gopal

The Human Ethics Committee advises that your research proposal "Sterilisation and reuse of medical devices in Nepal: a patient safety concern" has been considered and approved.

Please note that this approval is subject to the incorporation of the amendments you have provided in your email of 10 December 2015.

Best wishes for your project.

Yours sincerely

Lindsey MacDonald
Chair
University of Canterbury Human Ethics Committee

APPENDIX 13: UNIVERSITY OF CANTERBURY HUMAN ETHICS COMMITTEE APPROVAL LETTER (AMENDMENT)

UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

HUMAN ETHICS COMMITTEE

Secretary, Rebecca Robinson
Telephone: +64 03 364 2987, Extn 45588
Email: human-ethics@canterbury.ac.nz

Ref: HEC 2015/139

24 March 2016

Gopal Panta
School of Health Sciences
UNIVERSITY OF CANTERBURY

Dear Gopal

Thank you for your request for an amendment to your research proposal "Sterilisation and reuse of medical devices in Nepal: a patient safety concern" as outlined in your email dated 21st March 2016.

I am pleased to advise that this request has been considered and approved by the Human Ethics Committee.

Yours sincerely

Lindsey MacDonald
Chair, Human Ethics Committee

APPENDIX 14: NEPAL HEALTH RESEARCH COUNCIL APPROVAL LETTER

Government of Nepal

Nepal Health Research Council (NHRC)

Ref. No.: 1297

18 February 2016

Mr. Gopal Panta
Principal Investigator
University of Canterbury
New Zealand

Ref: **Approval of Research Proposal** entitled **Understanding sterilization and reuse of medical devices in Nepal**

Dear Mr. Panta,

It is my pleasure to inform you that the above-mentioned proposal submitted on 19 January 2016 (**Reg.no. 13/2016** please use this Reg. No. during further correspondence) has been approved by NHRC Ethical Review Board on 17 February 2016.

As per NHRC rules and regulations, the investigator has to strictly follow the protocol stipulated in the proposal. Any change in objective(s), problem statement, research question or hypothesis, methodology, implementation procedure, data management and budget that may be necessary in course of the implementation of the research proposal can only be made so and implemented after prior approval from this council. Thus, it is compulsory to submit the detail of such changes intended or desired with justification prior to actual change in the protocol.

If the researchers require the transfer of bio-samples to other countries, they should apply to the NHRC for permission. The researchers will not be allowed to ship any raw/crude human biomaterial outside the country; only extracted and amplified samples can be taken to labs outside of Nepal for further study, as per the protocol submitted and approved by the NHRC.

Further, the researchers are directed to strictly abide by the National Ethical Guidelines published by NHRC during the implementation of their research proposal and submit progress report and full or summary report upon completion.

As per your research proposal, the total research amount is **Self-Funded** and accordingly the processing fee amount to **NRs. 10,855.00.** It is acknowledged that the above-mentioned processing fee has been received at NHRC.

If you have any questions, please contact the Ethical Review M & E section of NHRC.

Thanking you,

.....
Dr. Khem Bahadur Karki
Member-Secretary

APPENDIX 15: NEPAL HEALTH RESEARCH COUNCIL APPROVAL LETTER (AMENDMENT)

Government of Nepal

Nepal Health Research Council (NHRC)

Estd. 1991

Ref. No.: 1562

31 March 2016

Mr. Gopal Panta
Principal Investigator
University of Canterbury
New Zealand

Subject: **Approval of requested amendment** for research proposal entitled **Understanding sterilization and reuse of medical devices in Nepal**

Dear Mr. Panta,

The meeting of Ethical Review Board of Nepal Health Research Council held on 16 March 2016 discussed about the amendment requested on 21 March 2016. The meeting has approved the revised data collection tools in the above- mentioned research project.

If you have any queries, please feel free to contact the Ethical Review M & E section of NHRC.

Thanking you.

Dr. Khem Bahadur Karki
Member-Secretary

Tel: +977 1 4254220, Fax: +977 1 4262469, Ramshah Path, PO Box: 7626, Kathmandu, Nepal
Website: http://www.nhrc.org.np, E-mail: nhrc@nhrc.org.np

APPENDIX 16: INFORMATION SHEET FOR HOSPITALS PARTICIPATING IN THE STUDY (ENGLISH VERSION)

School of Health Sciences
Telephone: +64 3 343 9606
Email: gopal.panta@pg.canterbury.ac.nz
Date: _____

Sterilization and Reuse of Medical Devices in Nepal: A Patient Safety Concern
Information Sheet for Hospitals Participating in the Research

My name is Gopal Panta. Currently, I am doing a PhD in Health Sciences in University of Canterbury, Christchurch, New Zealand. The purpose of my research project is to understand the current situation relating to sterilization and reuse of medical devices in primary and secondary care hospitals in Nepal. The research will focus particularly on steam heat sterilization (autoclaving) of medical devices. The findings of the research are expected to be useful in improving sterilization of medical devices in Nepal and reducing healthcare associated infections.

I would like to invite this hospital to participate in the project and request you to allow me to conduct a survey among healthcare staff, to observe steam sterilization practices, and to test steam sterilization practices using chemical and biological indicators.

The hospital may receive a copy of the project results by contacting the researcher at the conclusion of the project.

Participation is voluntary and the hospital has the right to withdraw at any stage without penalty. If hospital withdraws, I will remove all information relating to this hospital from my files. However, once the data from this hospital is combined with data from other hospitals, information cannot be removed because it is not identifiable.

The results of the project are likely to be published, but nothing published or retained in my files will be able to connect any data from questionnaire and tools to this hospital and the staff. To ensure anonymity, no identifying information of the hospital and the staff will be collected. Only the researcher will have access to the data. Completed questionnaire and tools will be stored securely in a locked cabinet and all electronic data will be stored on a password protected computer. The data will be destroyed 10 years after the completion of my PhD. A thesis is a public document and will be available through the University of Canterbury Library, but my thesis will not identify any information specific to this hospital and any of the answers to questions on the questionnaires completed by the hospital staff.

The project is being carried out as a requirement for the degree of Doctor of Philosophy in Health Sciences by Gopal Panta under the supervision of Prof. Ann Richardson and Prof. Ian Shaw, who can be contacted at ann.richardson@canterbury.ac.nz &

ian.shaw@canterbury.ac.nz. They will be pleased to discuss any concerns you may have about participation in the project.

This project has been reviewed and approved by the University of Canterbury Human Ethics Committee and Nepal Health Research Council, and participants should address any complaints to The Chair, Human Ethics Committee, University of Canterbury, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz).

If you agree to participate in the study, please complete the consent form and return it to me (I will be nearby when you sign the consent form).

Gopal Panta

APPENDIX 17: INFORMATION SHEET FOR HOSPITALS PARTICIPATING IN THE STUDY (NEPALI VERSION)

स्कुल अफ हेल्थ साइन्सेज
टेलिफोन: +६४ ३ ३४३ ९६०६
इमेल: gopal.panta@pg.canterbury.ac.nz
मिति_____

मेडिकल औजारहरुको निर्मलिकरण तथा पुन:प्रयोग-बिरामिको सुरक्षा सम्बन्धि एउटा बिषय
अनुसन्धानमा सहभागिहुने अस्पतालहरुकालागि लागि जानकारि

मेरो नाम गोपाल पन्त हो। हाल म यूनिभर्सिटी अफ क्यान्टेरबरि, क्राइस्टचर्च, न्यू जील्याण्डमा श्वास्थ्य बिज्ञान बिषयमा विध्यावारिधि गर्दै छु। मेरो अनुसन्धानको उदेश्य नेपालका प्राथमिक र दोस्रो श्रेणीका अस्पतालहरुमा मेडिकल औजारहरुको निर्मलिकरण तथा पुन: प्रयोगको बर्तमान अवस्था बुझ्नुरहेको छ। यो अनुसन्धान मेडिकल औजारहरुको वाष्पिकरणद्वारा गरिने निर्मलिकरण (अटोक्लेभीङ्) मा केन्द्रित रहने छ। यस अनुसन्धानका निष्कर्षहरु नेपालमा मेडिकल औजारहरुको निर्मलिकरणमा सुधार ल्याउन तथा श्वास्थ्य संस्थाबाट हुने संक्रमण न्युनिकरण गर्न उपयोगि हुने आशा गरिएको छ।

म यस अस्पताललाई यस परियोजनामा सहभागी हून आमन्त्रण गर्दछु । मलाई यस अस्पतालका स्वास्थ्य कार्यकर्ताहरुमा एउटा सर्वेक्षण गर्न, वाष्पिकरणद्वारा गरिने निर्मलिकरण अभ्यासहरुको अवलोकन गर्न र जैविक तथा रसायनिक बिधिद्वारा निर्मलिकरण अभ्यासहरुको परिक्षण गर्नका लागि अनुमति दिनुहुन अनुरोध गर्दछु।

अस्पतालले यस अनुसन्धानका परिणामहरु अनुसन्धानकर्तालाई परियोजनाको अन्त्यमा सम्पर्क गरि प्राप्त गर्न सक्नेछ।

सहभागिता श्वेच्छिक हूनेछ र अस्पताललाई यसबाट कुनै पनि समय बिना कुनै असर बाहिरिने अधिकार छ। यदि अस्पताल यसबाट बाहिरियो भने यस अस्पतालसंग सम्बन्धित सम्पूर्ण जानकारिहरु मेरो रेकर्डबाट हटाउने छु। यध्यपि यस अस्पतालका डाटालाई अन्य अस्पतालका डाटासंग जम्मा गरिसकेपछि भने जानकारिहरु चिन्न र हटाउन सकिने छैन।

यस परियोजनाका पारिणामहरु प्रकाशित हून सक्छन् तर कुनै पनि प्रकाशित वा मसंग रहेका सामग्रीहरुले यस अस्पताल र यहाँ कार्यरत कर्मचारिहरुलाई चिन्न सकिने छैन । जानकारिहरुलाई नचिनिने बनाउन अस्पताल र कर्मचारिहरुलाई चिनाउने कुनै पनि जानकारिहरु लिइने छैन। डाटामा अनुसन्धानकर्ताको मात्र पहूँच हूनेछ। पुरागरिएका प्रश्नावलि तथा सामग्रिहरु ताल्चा लगाएको दराजमा र इलेक्ट्रोनिक् फाइलहरु पासवर्ड भएको कम्प्यूटरमा सुरक्षित राखिने छ। डाटाहरुहरु मेरो विध्यावारिधि सकिएको दश बर्ष पछि नष्ट गरिने छ। सोधपत्र एउटा सार्वजनिक दस्तावेज हूनेछ र यो यूनिभर्सिटी अफ क्यान्टेरबरिको पुस्तकालयमा उपलब्ध हूनेछ तर सोधपत्रमा यस अस्पताल विशेष जानकारिहरु तथा यहाँका कर्मचारिहरुले दिनु भएका कुनै पनि प्रश्नका उत्तरहरु ब्यक्तिगरुपमा चिन्न सकिने छैन।

यो परियोजना प्रा. एन् रिचर्ड्सन् र प्रा. इयन शको सुपरिवेक्षणमा गोपाल पन्तले श्वास्थ्य विज्ञानमा विध्यावारिधि गर्नका लागि आवश्यकता स्वरुप गर्न लागिएको हो। सुपरिवेक्षकहरुलाइ ann.richardson@canterbury.ac.nz र ian.shaw@canterbury.ac.nz मा सम्पर्क गर्न सकिन्छ। यस परियोजनामा तपाइँको सहभागीता बारे कुनै जिज्ञासा छ भने उहाँहरुलाई सम्पर्क गर्न सक्नु हुन्छ।

यस परियोजनाले युनिभर्सिटी अफ क्यान्टरबरिको ह्युमन एथिक्स् कमिटिबाट र नेपाल श्वास्थ्य अनुसन्धान केन्द्रबाट स्वीकृती पाइसकेको छ र सहभागीहरुको कुनै गुनासो निम्न ठेगानामा सम्पर्क राख्न सकिन्छ: प्रमुख, ह्युमन एथिक्स् कमिटि, युनिभर्सिटी अफ क्यान्टरबरि, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz).

यदि तपाइँ यस अध्ययनमा सहभागी ह्न सहमत ह्नुह्न्छ भने मन्जुरी फारम भरेर मलाई दिनुहोला (तपाइँले मन्जुरी फारममा हस्ताक्षर गरिरहँदा म छेउमै हुनेछु)।

APPENDIX 18: CONSENT FORM FOR MEDICAL SUPERINTENDENT OR EQUIVALENT OF THE HOSPITALS PARTICIPATING IN THE STUDY (ENGLISH VERSION)

School of Health Sciences
Telephone: +64 3 343 9606
Email: gopal.panta@pg.canterbury.ac.nz

UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

Understanding Sterilization and Reuse of Medical Devices in Nepal
Consent Form for Medical Superintendent or Equivalent

I have been given a full explanation of this project and have had the opportunity to ask questions.

I understand what is required of the hospital if we agree to take part in the research.

I understand that participation is voluntary and the hospital may withdraw at any time without no implications for it. Withdrawal of participation will also include the withdrawal of any information this hospital's staff have provided should this remain practically achievable.

I understand that any information and opinion the hospital staff provide will be kept confidential to the researcher and that any published or reported results (including in a PhD thesis) will not identify the hospital or the staff member. I understand that a thesis is a public document and will be available through the University of Canterbury Library.

I understand that all data collected for the study will be kept in locked and secure facilities and in password protected electronic form and will be destroyed after ten years.

I understand that hospital is able to receive a report on the findings of the study by contacting the researcher at the conclusion of the project.

I understand that hospital can contact the researcher Gopal Panta, School of Health Sciences, University of Canterbury (email: gopal.panta@pg.canterbury.ac.nz, phone: +6433439606) or supervisors Prof. Ann Richardson and Prof. Ian Shaw (email: ann.richardson@canterbury.ac.nz & ian.shaw@canterbury.ac.nz; phone: + 6433643786, +6433643105) for further information. If there are any complaints, hospital can contact the Chair of the University of Canterbury Human Ethics Committee, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz)

☐ I would like to receive a copy of a summary of the research findings through this email

_____

By signing below, I agree participate in this research project.

Name_____Hospital _____ Date_____Signature_____

Please return this form to the researcher Gopal Panta in person immediately after you sign it.

Gopal Panta
School of Health Sciences
University of Canterbury
Private Bag 4800
Christchurch 8140

APPENDIX 19: CONSENT FORM FOR MEDICAL SUPERINTENDENT OR EQUIVALENT OF THE HOSPITALS PARTICIPATING IN THE STUDY (NEPALI VERSION)

स्कुल अफ हेल्थ साइन्सेज
टेलिफोन: +६४ ३ ३४३ ९६०६
इमेल: gopal.panta@pg.canterbury.ac.nz

UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

मेडिकल औजारहरुको निर्मलिकरण तथा पुन:प्रयोग–बिरामिको सुरक्षा सम्बन्धि एउटा बिषय
अस्पताल प्रमुखका लागि मन्जुरी पत्र

मलाइ यस परियोजना को बारेमा पूर्ण विवरण दिइएको छ र मलाइ यसको बारेमा प्रश्न सोध्ने मौका पनि दिइएको छ।

यदि हामी यस अनुसन्धानमा सहभागि हुन सहमत भयौं भने यस अस्पतालबाट के आबश्यक पर्छ भन्ने मैले बुझेको छु।

मैले बुझेको छु कि अस्पतालको सहभागिता श्वेच्छिक हो र अस्पताल कुनै पनि बेला बिना कुनै असर यस अनुसन्धानबाट बाहिरिन सक्छ। अस्पताल यस अनुसन्धानबाट बाहिरिनु भनेको अस्पतालका कर्मचारिहरुले दिएका सबै जानकारिहरु पनि हटाइनु (ब्यबाहारिकरुपमा सम्भव भएसम्म) हो।

मैले बुझेको छु कि अस्पतालका कर्मचारिहरुले दिएका कुनै पनि जानकारि र बिचारहरु अनुसन्धानकर्तालाइ मात्र थाहा हुनेगरि गोप्य रखिने छ र कुनै पनि छापिने वा प्रकाशित गरिने विवरणहरुमा (विध्यावारिधिको सोधपत्रमा समेत) अस्पताल र कर्मचारिहरुको नाम उल्लेख गरिने छैन। मलाइ थाहा छ सोधपत्र एउटा सार्बजनिक दस्तावेज हो र यो युनिभर्सिटी अफ क्यान्टरबरिको पुस्तकालयमा उपलब्ध हुनेछ।

मलाइ थाहा छ अध्ययनको क्रममा संकलन गरिएका सबै तथ्याङ्कहरु ताल्चा लगाएको ठाउँमा र पासवर्ड भएको कम्प्युटरमा सुरक्षित रुपमा राखिने छ र सबै तथ्याङ्कहरु दश बर्ष पछि नष्ट गरिने छ।

मैले बुझेको छु कि अस्पतालले यस परियोजनाको अन्त्यमा अनुसन्धानकर्तालाई सम्पर्क गरेर यस अध्ययनका निष्कर्सहरुको विवरण प्राप्त गर्न सक्ने छ।

मैले बुझेको छु कि अस्पतालले अनुसन्धानकर्ता गोपाल पन्त लाइ निम्न ठेगानामा सम्पर्क राख्न सक्ने छ। स्कुल अफ हेल्थ साइन्सेज, युनिभर्सिटी अफ क्यान्टरबरि, इमेल: gopal.panta@pg.canterbury.ac.nz, टेलिफोन: +६४३३४३९६०६। त्यसैगरि यस अनुसन्धानका सुपरिवेक्षकहरु प्रा. एन रिचर्ड्सन् र प्रा. इयन श (इमेल: ann.richardson@canterbury.ac.nz र ian.shaw@canterbury.ac.nz; टेलिफोन: +६४३३६४३७८६, +६४३३६४३१०५) लाइ पनि सम्पर्क गर्ने सक्ने छ। कुनै गुनासो भएको खन्डमा अस्पतालले युनिभर्सिटी अफ क्यान्टरबरि ह्युमन एथिक्स् कमिटिका प्रमुखलाइ Private Bag 4800, Christchurch मा सम्पर्क रख्न सक्ने छ।

☐ म यस अनुसन्धानका निष्कर्सहरुको सारांशको एक प्रतिलिपि यो ईमेलबाट प्राप्त गर्न चाहन्छु।

_____

निम्न स्थानमा हस्ताक्षर गर्दै म यस अनुसन्धानमा सहभागि हुन सहमत हुन्छु।

नाम_____ मिति_____ हस्ताक्षर_____

यस फारममा हस्ताक्षर गरिसकेपछि अनुसन्धानकर्ता गोपाल पन्तलाइ तत्कालै फिर्ता दिनु होला।

गोपाल पन्त
स्कुल अफ हेल्थ साइन्सेज, युनिभर्सिटी अफ क्यान्टरबरि, Private Bag 4800, Christchurch 8140

APPENDIX 20: INFORMATION SHEET FOR HEALTHCARE WORKERS PARTICIPATING IN THE SURVEY (ENGLISH VERSION)

School of Health Sciences
Telephone: +64 3 343 9606
Email: gopal.panta@pg.canterbury.ac.nz
Date: _____

Understanding Sterilization and Reuse of Medical Devices in Nepal
Information Sheet for Healthcare Workers Participating in the Research

My name is Gopal Panta. Currently, I am doing a PhD in Health Sciences in University of Canterbury, Christchurch, New Zealand. The purpose of my research project is to understand the current situation of sterilization and reuse of medical devices in primary and secondary care hospitals in Nepal. The research will focus on steam heat sterilization (autoclaving) of medical devices. The findings of the research are expected to be useful in improving sterilization of medical devices in Nepal and help to reduce healthcare-associated infections.

I would like to invite you to participate in a survey which aims to understand the knowledge and attitude of healthcare workers towards sterilization and the reuse of medical devices. You will be provided with a written questionnaire and asked to complete the questionnaire by yourself. It will take about 15 minutes to complete the questionnaire, and I ask that you return the questionnaire to me in person immediately after you complete it.

If you would like a copy of the project results please contact me by email or post (my contact details are at the top of this page).

Participation is voluntary and you have the right to withdraw at any stage with no implications for you. If you withdraw, I will remove all information relating to you from my records (this information only relates to the answers to questions on your questionnaire – no personal information will be collected). However, once the data from your completed questionnaire is combined with data from other questionnaires your information cannot be removed because it is not identifiable as yours.

The results of the project are likely to be published, but nothing published or retained in my files will be able to connect any data from your questionnaire to you personally. To ensure anonymity, no personal information including name, home address and date of birth will be collected. Only the researcher will have access to the data. Completed questionnaire will be stored securely in a locked cabinet and all electronic data will be stored on a password protected computer. The data will be destroyed 10 years after the completion of my PhD. A thesis is a public document and will be available through the University of Canterbury Library, but my thesis will not identify any of the answers to questions on your questionnaire to you personally.

The project is being carried out as a requirement for the degree of Doctor of Philosophy in Health Sciences by Gopal Panta under the supervision of Prof. Ann Richardson and Prof. Ian Shaw, who can be contacted at ann.richardson@canterbury.ac.nz & ian.shaw@canterbury.ac.nz. They will be pleased to discuss any concerns you may have about participation in the project.

This project has been reviewed and approved by the University of Canterbury Human Ethics Committee and Nepal Health Research Council, and participants should address any complaints to The Chair, Human Ethics Committee, University of Canterbury, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz).

If you agree to participate in the study, please complete the consent form and return it to me (I will be nearby when you sign the consent form).

Gopal Panta

APPENDIX 21: INFORMATION SHEET FOR HEALTHCARE WORKERS PARTICIPATING IN THE SURVEY (NEPALI VERSION)

स्कुल अफ हेल्थ साइन्सेज
टेलिफोन: +६४ ३ ३४३ ९६०६
इमेल: gopal.panta@pg.canterbury.ac.nz
मिति_____

UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

मेडिकल औजारहरुको निर्मलिकरण तथा पुन:प्रयोग
अनुसन्धनमा सहभागिहुने श्वास्थ्य कार्यकर्ताहरुका लागि जानकारि

मेरो नाम गोपाल पन्त हो। हाल म युनिभर्सिटी अफ क्यान्टेरबरि, क्राइस्टचर्च, न्यु जील्याण्डमा श्वास्थ्य बिज्ञान बिषयमा विध्यावारिधि गर्दै छु। मेरो अनुसन्धानको उद्देश्य नेपालका प्रथम र दोस्रो श्रेणीका अस्पतालहरुमा मेडिकल औजारहरुको निर्मलिकरण तथा पुन: प्रयोगको बर्तमान अवस्था बुझ्नुरहेको छ। यो अनुसन्धान मेडिकल औजारहरुको वाष्पिकरणद्वारा गरिने निर्मलिकरण (अटोक्लेभीङ्) मा केन्द्रित रहने छ। यस अनुसन्धानका निष्कर्षहरु नेपालमा मेडिकल औजारहरुको निर्मलिकरण मा सुधार ल्याउन तथा श्वास्थ्य संस्थाबाट हुने संक्रमण न्युनिकरणमा उपयोगि हुने आशा गरिएको छ।

म तपाइँलाई मेडिकल औजारहरुको निर्मलिकरण तथा पुन:प्रयोग सम्बन्धि एउटा सर्वेक्षणमा सहभागि हुन आमन्त्रण गर्दछु। यस सर्वेक्षणको उद्देश्य यस बिषयमा स्वास्थ्य कार्यकर्ताहरुको ज्ञान तथा मनोवृत्ति बुझ्नु रहेको छ। तपाइँलाइ एउटा लिखित प्रश्नावलि उपलब्ध गराइने छ र त्यसलाई तपाइँआफैंद्वारा उत्तर दिइ पुरा गर्न अनुरोध गरिने छ। प्रश्नावलि पुरा गर्न गर्न १५ मिनेट जति समय लाग्ने छ र पुरा गरिसकेपछि तत्कालै मलाई भेटेर प्रश्नावलि फिर्ता गरिदिन अनुरोध गर्दछु।

तपाइँलाई यस अनुसन्धानको परिणामहरु चाहिने भए मलाइ ईमेल वा हुलाक बाट सम्पर्क गर्न सक्नु हुनेछ (मेरो सम्पर्क ठेगाना माथि दिइएको छ)।

सहभागिता श्वेच्छिक हुनेछ र तपाइँलाई यसबाट कुनै पनि समय बिना कुनै असर बाहिरिने अधिकार छ। यदि तपाइँ यसबाट बाहिरिनु भयो भने तपाइँसंग सम्बन्धित सम्पूर्ण जानकारिहरु मेरो रेकर्डबाट हटाउने छु (जानकारिहरु भन्नाले तपाइँको प्रश्नावलिमा भएका प्रश्नका उत्तरहरुसँग मात्र सम्बन्धित छ, अन्य कुनै पनि ब्यक्तिगत जानकारिहरु लिइने छैन)। यद्ध्यपि पुरा गरिएको प्रश्नावलिका जानकारिहरुलाई अन्य प्रश्नावलिका जानकारिहरुसंग जम्मा गरिसकेपछि भने तपाइँका जानकारिहरु चिन्न र हटाउन सकिने छैन।

यस परियोजनाका पारिणामहरु प्रकाशित हुन सक्छन् तर कुनै पनि प्रकशित वा मसंग रहेका सामग्रीहरुले तपाइँमा तपाइँलाई ब्यक्तिगतरुपमा चिन्न सकिने छैन। तपाइँले दिनुभएका जानकारिहरु नचिनिने बनाउन तपाइँको नाम, घरको ठेगाना र जन्म मिति लिइने छैन। डाटामा अनुसन्धानकर्ताको मात्र पहुँच हुनेछ। पूरागरिएका प्रश्नावलिहरु ताल्चा लगाएको दराजमा र इलेक्ट्रोनिक् फाइलहरु पासवर्ड भएको कम्प्यूटरमा सुरक्षित राखिने छ।
डाटा मेरो विध्यावारिधि सकिएको दश बर्ष पछि नस्ट गरिने छ। सोधपत्र एउटा सार्वजनिक दस्तावेज हुनेछ र यो युनिभर्सिटी अफ क्यान्टेरबरिको पुस्तकालयमा उपलब्ध हुनेछ तर सोधपत्रमा तपाइँले दिनु भएका कुनै पनि प्रश्नका उत्तरहरु ब्यक्तिगरुपमा चिन्न सकिने छैन।

यो परियोजना प्रा. एन् रिचर्ड्सन् र प्रा. इयन शको सुपरिवेक्षणमा गोपाल पन्तले श्वास्थ्य विज्ञानमा विध्यावारिधि गर्नका लागि आवश्यकता स्वरुप गर्न लागिएको हो। सुपरिवेक्षकहरुलाइ ann.richardson@canterbury.ac.nz & ian.shaw@canterbury.ac.nz मा सम्पर्क गर्न सकिन्छ। यस परियोजनामा तपाइँको सहभागिता बारे कुनै जिज्ञासा छ भने उहाँहरुलाई सम्पर्क गर्न सक्नु हुन्छ।

यस परियोजनाले युनिभर्सिटी अफ क्यान्टरबरिको ह्युमन एथिक्स् कमिटिबाट र नेपाल श्वास्थ्य अनुसन्धान केन्द्रबाट स्वीकृती पाइसकेको छ र सहभागिहरुको कुनै गुनासो निम्न ठेगानामा सम्पर्क राख्न सकिन्छ:
प्रमुख, ह्युमन एथिक्स् कमिटि, युनिभर्सिटी अफ क्यान्टरबरि, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz).

यदि तपाइँ यस अध्ययनमा सहभागि ह्न सहमत ह्नुह्न्छ भने मन्जुरी फारम भरेर मलाई दिनुहोला (तपाइँले मन्जुरी फारममा हस्ताक्षर गरिरहँदा म छेउमै हुनेछु)।

APPENDIX 22: CONSENT FORM FOR HEALTHCARE WORKERS PARTICIPATING IN THE SURVEY (ENGLISH VERSION)

School of Health Sciences
Telephone: +64 3 343 9606
Email: gopal.panta@pg.canterbury.ac.nz

UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

Understanding Sterilization and Reuse of Medical Devices in Nepal
Consent Form for Healthcare Workers

I have been given a full explanation of this project and have had the opportunity to ask questions.

I understand what is required of me if I agree to take part in the research.

I understand that participation is voluntary and I may withdraw at any time without no implications for me. Withdrawal of participation will also include the withdrawal of any information I have provided should this remain practically achievable.

I understand that any information or opinions I provide will be kept confidential to the researcher and that any published or reported results (including in a PhD thesis) will not identify the participants or the hospital they are working in. I understand that a thesis is a public document and will be available through the UC Library.

I understand that all data collected for the study will be kept in locked and secure facilities and in password protected electronic form and will be destroyed after ten years.

I understand that I am able to receive a report on the findings of the study by contacting the researcher at the conclusion of the project.

I understand that I can contact the researcher Gopal Panta, School of Health Sciences, University of Canterbury (email: gopal.panta@pg.canterbury.ac.nz, phone: +6433439606) or supervisors Prof. Ann Richardson and Prof. Ian Shaw (email: ann.richardson@canterbury.ac.nz & ian.shaw@canterbury.ac.nz; phone: + 6433643786, +6433643105) for further information. If I have any complaints, I can contact the Chair of the University of Canterbury Human Ethics Committee, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz)

☐ I would like to receive a copy of a summary of the research findings through this email

_____

By signing below, I agree to participate in this research project.

Name_____ Date_____
Signature_____

Please return this form to the researcher Gopal Panta in person immediately after you sign it.

Gopal Panta
School of Health Sciences
University of Canterbury
Private Bag 4800
Christchurch 8140

APPENDIX 23: CONSENT FORM FOR HEALTHCARE WORKERS PARTICIPATING IN THE SURVEY (NEPALI VERSION)

स्कुल अफ हेल्थ साइन्सेज
टेलिफोन: +६४ ३ ३४३ ९६०६
इमेल: gopal.panta@pg.canterbury.ac.nz

मेडिकल औजारहरुको निर्मलिकरण तथा पुन:प्रयोग: बिरामिको सुरक्षा सम्बन्धि एउटा बिषय
स्वास्थ्य कार्याकर्ताहरुका लागि मन्जुरी पत्र

मलाइ यस परियोजना को बारेमा पूर्ण विवरण दिइएको छ र मलाइ यसको बारेमा प्रश्न सोध्ने मौका पनि दिइएको छ।

यदि म यस अनुसन्धानमा सहभागि हुन सहमत भएँ भने मैले के गर्नु पर्छ भन्ने बुझेको छु।

मैले बुझेको छु कि मेरो सहभागिता श्वेच्छिक हो र म कुनै पनि बेला बिना कुनै असर यस अनुसन्धानबाट बाहिरिन सक्छु। म यस अनुसन्धानबाट बाहिरिनु भनेको मैले दिएको सबै जानकारिहरु पनि हटाइनु (ब्यबाहारिकरुपमा सम्भव भएसम्म) हो।

मैले बुझेको छु कि मैले दिएका कुनै पनि जानकारि र बिचारहरु अनुसन्धानकर्तालाइ मात्र थाहा हुनेगरि गोप्य रखिने छ र कुनै पनि छापिने वा प्रकाशित गरिने विवरणहरुमा (विध्यावारिधिको सोधपत्रमा समेत) सहभागिको र सहभागि काम गरिरहेको अस्पातालको नाम उल्लेख गरिने छैन। मलाइ थाहा छ सोधपत्र एउटा सार्बजनिक दस्तावेज हो र यो युनिभर्सिटी अफ क्यान्टरबरिको पुस्तकालयमा उपलब्ध हुनेछ।

मलाइ थाहा छ अध्ययनको क्रममा संकलन गरिएका सबै तथ्याङ्कहरु ताल्चा लगाएको ठाउँमा र पासवर्ड भएको कम्प्युटरमा सुरक्षित रुपमा राखिने छ र सबै तथ्याङ्कहरु दश बर्ष पछि नष्ट गरिने छ।

मैले बुझेको छु कि मैले यस परियोजनाको अन्त्यमा अनुसन्धानकर्तालाई सम्पर्क गरेर यस अध्ययनका निष्कर्सहरुको विवरण प्राप्त गर्न सक्ने छु।

मैले बुझेको छु कि मैले अनुसन्धानकर्ता गोपाल पन्त लाइ निम्न ठेगानामा सम्पर्क राख्न सक्ने छु। स्कुल अफ हेल्थ साइन्सेज, युनिभर्सिटी अफ क्यान्टरबरि, इमेल: gopal.panta@pg.canterbury.ac.nz, टेलिफोन: +६४३३४३९६०६। त्यसैगरि यस अनुसन्धानका सुपरिवेक्षकहरु प्रा. एन् रिचर्ड्सन् र प्रा. इयन श (इमेल: ann.richardson@canterbury.ac.nz र ian.shaw@canterbury.ac.nz; टेलिफोन: +६४३३६४३७८६, +६४३३६४३१०५) लाइ पनि सम्पर्क गर्ने सक्ने छु।

मेरो कुनै गुनासो भएमा युनिभर्सिटी अफ क्यान्टरबरि ह्युमन एथिक्स् कमिटिका प्रमुखलाइ Private Bag 4800, Christchurch मा सम्पर्क रख्न सक्ने छु।

☐ म यस अनुसन्धानका निष्कर्सहरुको सारांशको एक प्रतिलिपि यो ईमेलबाट प्राप्त गर्न चाहन्छु।

_____

निम्न स्थानमा हस्ताक्षर गर्दै म यस अनुसन्धानमा सहभागि हुन सहमत हुन्छु।

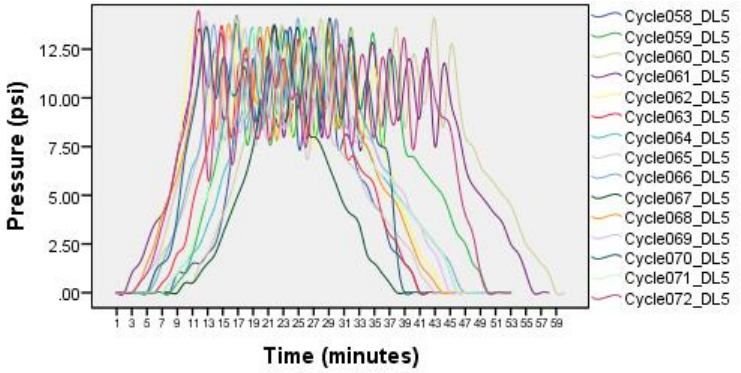
नाम_____ मिति_____ हस्ताक्षर_____

यस फारममा हस्ताक्षर गरिसकेपछि अनुसन्धानकर्ता गोपाल पन्तलाइ तत्कालै फिर्ता दिनु होला।

गोपाल पन्त
स्कुल अफ हेल्थ साइन्सेज, युनिभर्सिटी अफ क्यान्टरबरि, Private Bag 4800, Christchurch 8140

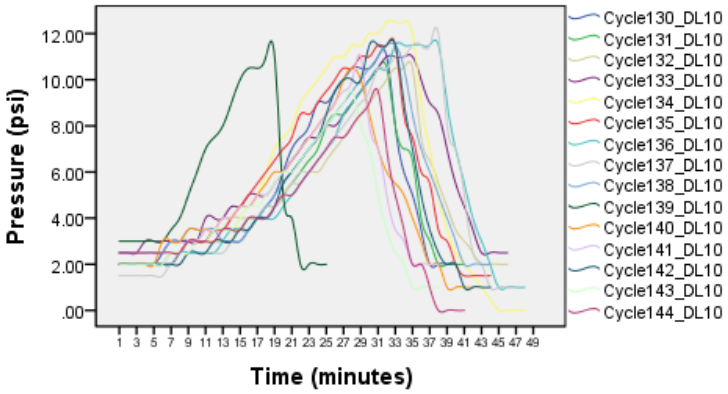
APPENDIX 24: PRESSURE CURVES OF AUTOCLAVE CYCLES FOR DIFFERENT HOSPITALS INCLUDED IN THE STUDY

District-level hospitals

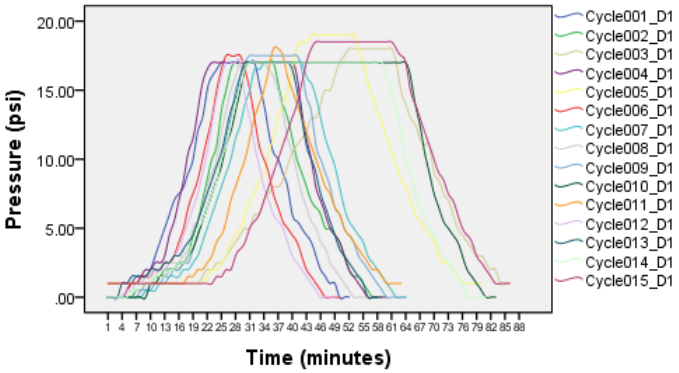


District-level

District-level

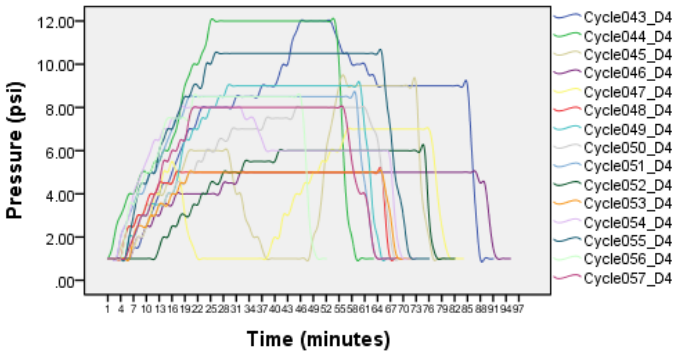


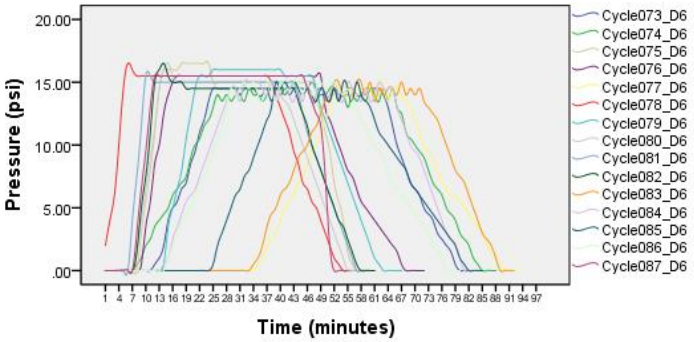
District hospitals



District Hospital 01

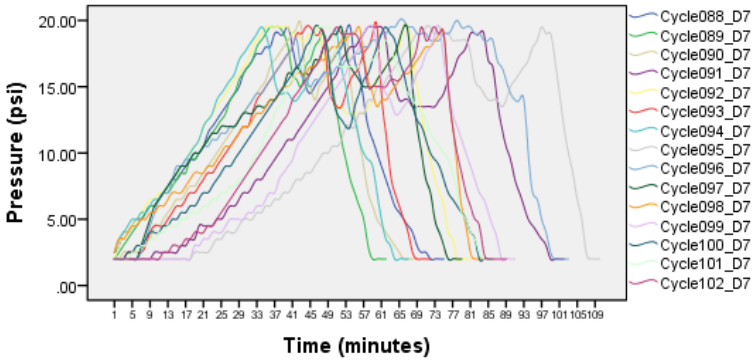
District Hospital 04

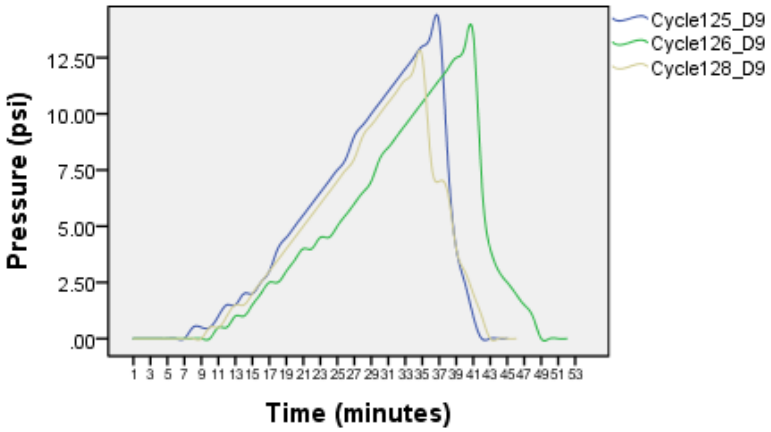




District Hospital 06

District Hospital 07

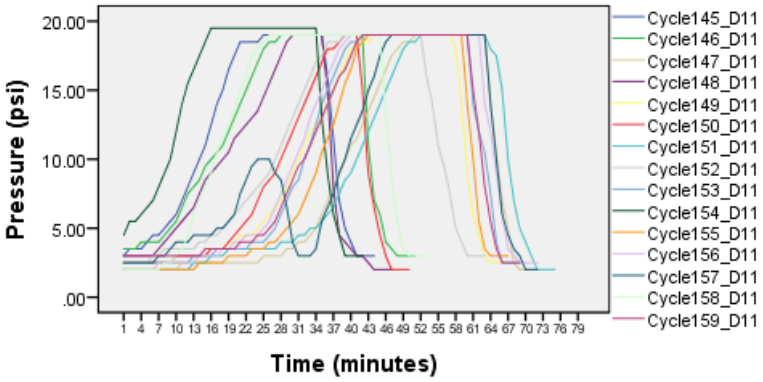


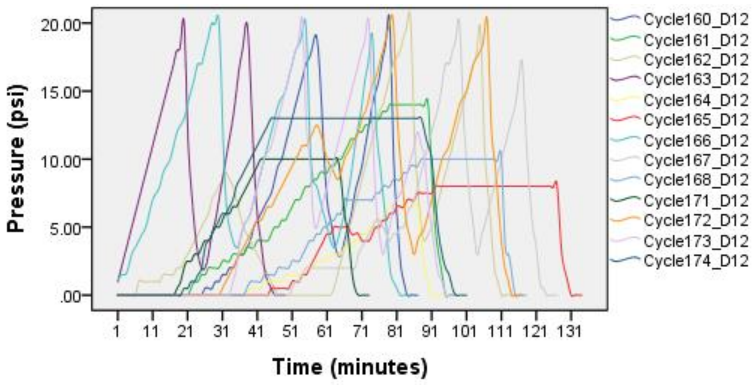


District Hospital 09

(Pressure readings could be recorded

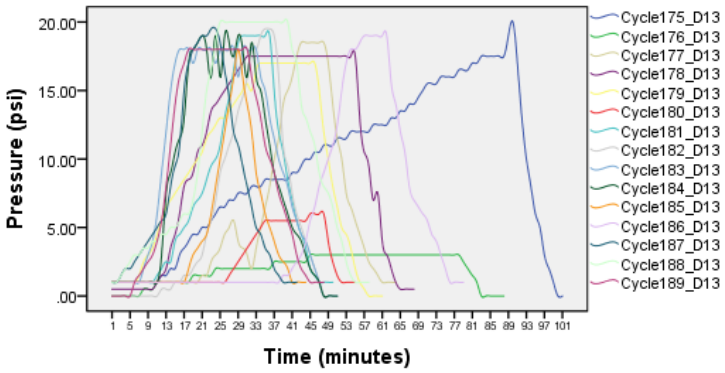
District Hospital 11



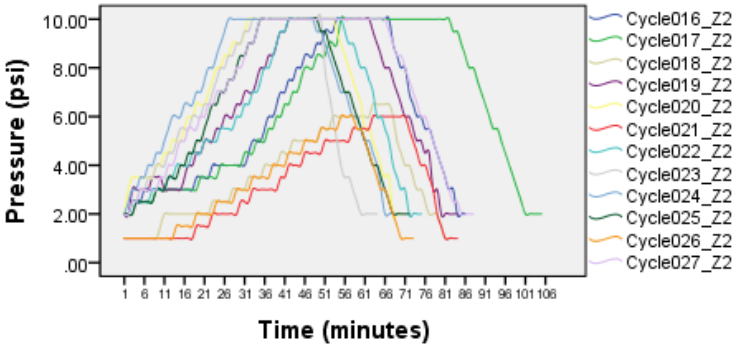


District Hospital 12

District Hospital 13

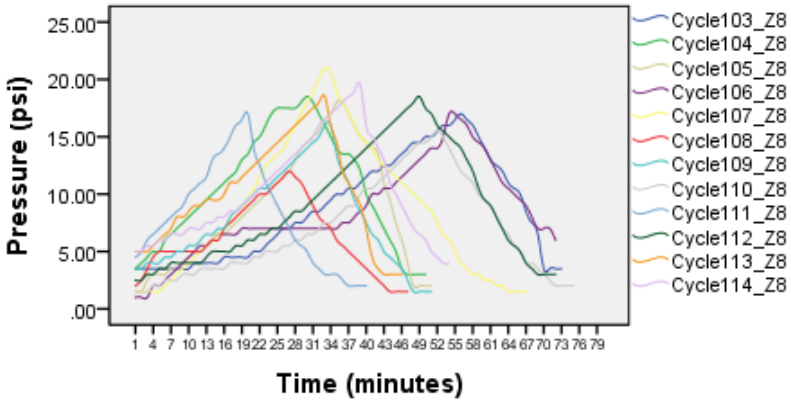


Zonal Hospitals



District Hospital 02

District Hospital 08



APPENDIX 25: BREAKDOWN OF THE AGE OF THE PARTICIPANTS PARTICPATING IN THE KNOWLEDGE AND ATTITUDE SURVEY

Age group	Number	Percent
Under 20	7	3.2
21-30	116	53.0
31-40	56	25.6
41-50	21	9.6
51-60	18	8.2
Age missing	1	0.5
Total	219	100.0

APPENDIX 26: HEALTHCARE WORKERS' KEY RECOMMENDATIONS FOR IMPROVING STERILIZATION AND REUSE OF MEDICAL DEVICES IN THEIR HOSPITALS

Themes	Healthcare workers' recommendations (on their own words)
Training and education	– *Training on infection prevention to all staff* – *Providing training to all staff involved in sterilization* – *Training of autoclave operator* – *One separate person should be given the responsibility of sterilization and training should be provided to that person* – *Providing training about infection prevention, methods of sterilization, and proper handling of infected and sterilized instruments* – *Providing adequate training on sterilization and reuse of medical devices to support staff involved in these procedures* – *Refresher training for all staff about sterilization* – *Proper training should be given to health workers about the use of sterilization technique and its hazards* – *Providing skill based training* – *Training related to sterilization and infection prevention should not only be focussed or given to lower level staff but all the staff should get chance for equal participation in it* – *Office assistants do not have complete knowledge; they need to be provided with new updates and knowledge.* – *Providing training to new staff responsible for operating autoclave* – *Creating awareness regarding health hazards related to reuse of unsterilized medical devices*
Human resources	– *Availability of separate staff for sterilization* – *Sincerity of the staff towards the sterilization process* – *Coordination between staff needs to be improved* – *Appointing focal person for sterilization as well as providing adequate staff* – *Increasing number of staff responsible for operating autoclave* – *Increasing trained manpower* – *Government should create position for CSSD*
Infrastructure	– *Availability of separate room for sterilization* – *Allocating a separate bigger room for autoclaving* – *Separate department for sterilization* – *By establishing CSSD supply unit* – *Establishment of disinfection department with an officer to monitor* – *Availability of adequate spaces would help for providing better services* – *There should be continuous supply of electricity* – *Due to the lack of spaces for storage, sterilization, cleaning and drying, we are not being able to follow infection prevention practices properly; availability of adequate spaces would help for providing better services*
Equipment and supplies	– *Availability of new medical devices* – *Providing sufficient medical devices* – *Timely maintenance of autoclave* – *Availability of good equipment* – *Sufficient supplies and autoclave* – *Availability of additional spare autoclave* – *By making an arrangement of a bigger autoclave* – *Using autoclave with modern technologies* – *We need additional autoclave* – *Availability of all equipment and resources*

	– *Appropriate equipment for sterilization* – *By adding sterilization instruments and repairing broken equipment* – *Availability of infection prevention materials* – *Mask, gloves, boots and Other PPEs should be made available to cleaning staff* – *New machine and separate room needed*
Supervision and monitoring	– *Monitoring and supervision of sterilization* – *Proper monitoring of autoclave use* – *Monitoring and assessment by concerned organization* – *There should be strong and effective monitoring on sterilization process* – *Strict monitoring and supervision* – *Need to monitor in each CSSD and ward; supervision plus monitoring is very necessary.* – *Doctors and nurses should monitor sterilization activities and help support staff improve the system*
Standard practices	– *Adequate cleaning and HLD* – *Adequate disinfection of medical devices* – *Adequate cleanliness in CSSD* – *Cleaning medical devices in soap water using a brush and then cleaning with clean water* – *Disinfection process which is done by immersing medical devices in 0.5% chlorine needs to be accurate* – *Regular use of 0.5% chlorine solution* – *Wrapping medical devices and then sterilizing them in recommended time and temperature* – *Giving attention to the cleanliness and starting chemical sterilization* – *Using alternative method of sterilization such as HLD* – *In my hospital, staff responsible for preparing chlorine solution do not prepare it appropriately no matter how much we teach; chlorine solution should be prepared by allowing it to sediment after mixing*